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Contents

Federal Register

Vol. 66, No. 226

Friday, November 23, 2001

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.
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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 66, No. 226
Friday, November 23, 2001

FEDERAL RESERVE SYSTEM

12 CFR Parts 211 and 265

[Regulation K; Docket No. R–0994]

International Banking Operations; Rules Regarding Delegation of Authority

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; correcting amendments.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting correcting amendments to the final rule published in the **Federal Register** of October 26, 2001, regarding international banking operations and the corresponding delegations of authority. The corrections clarify a number of provisions and correct a citation appearing in Subpart A, and restore a provision that was adopted in January 2001, but was inadvertently deleted from the rule.

DATES: Effective November 26, 2001.

FOR FURTHER INFORMATION CONTACT: Ann Misback, Assistant General Counsel (202/452–3788), or Alison MacDonald, Counsel (202/452–3236), Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: On October 17, 2001, the Board adopted final revisions to subparts A, B, and C of Regulation K, governing international banking operations and to corresponding rules regarding delegations of authority. (*See* 66 FR 54346, October 26, 2001). The final revisions become effective on November 26, 2001. This document makes the following corrections to those final revisions: (1) Clarifies, with respect to the second of five factors considered by the Board in acting on proposals by member banks to invest more than 10 percent of capital and surplus in Edge and agreement corporation subsidiaries, that amounts invested in and retained earnings of any foreign bank subsidiaries are to be included in the relevant capital calculation; (2) restores a provision on the protection of customer information by Edge and agreement corporations that was adopted in January 2001 and was inadvertently omitted from the rule; (3) adds a cross reference in the portfolio investment section of 211.8(c)(3) to the aggregate equity limit previously adopted by the Board set forth in section 211.10(a); (4) corrects a United States Code citation appearing in a footnote to section 211.9 of the rule; and (5) clarifies the scope of authority delegated to the Secretary of the Board of Governors of the Federal Reserve System and the Reserve Banks to approve applications by a member bank to invest more than 10 percent of capital and surplus in Edge and agreement corporation subsidiaries by incorporating Board-imposed conditions on the scope of that authority.

List of Subjects

12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 265

Authority delegations (Government agencies), Banks, banking, Federal Reserve System.

Accordingly, 12 CFR parts 211 and 265 are corrected by making the following correcting amendments:

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

1. Section 211.5 is amended as follows:

a. Paragraph (h)(2)(ii) is revised; and

b. A new paragraph (l) is added.

The revision and addition read as follows:

§ 211.5 Edge and agreement corporations.

* * * * *

(h) * * *

(2) * * *

(ii) The total capital invested by the bank in its Edge and agreement corporations when combined with retained earnings of the Edge and agreement corporations (including amounts invested in and retained earnings of any foreign bank subsidiaries) as a percentage of the bank's capital;

* * * * *

(l) *Protection of customer information.* An Edge or agreement corporation shall comply with the Interagency Guidelines Establishing Standards for Safeguarding Customer Information prescribed pursuant to sections 501 and 505 of the Gramm-Leach-Bliley Act (15 U.S.C. 6801 and 6805), set forth in appendix D–2 to part 208 of this chapter.

* * * * *

2. Section 211.8 is amended as follows:

a. Paragraphs (c)(3)(ii) and (iii) are respectively redesignated as paragraphs (c)(3)(iii) and (iv); and

b. A new paragraph (c)(3)(ii) is added.

The addition reads as follows:

§ 211.8 Investments and activities abroad.

* * * * *

(c) * * *

(3) * * *

(ii) *Aggregate Investment Limit.* Portfolio investments made under authority of this subpart shall be subject to the aggregate equity limit of § 211.10(a)(15)(iii).

* * * * *

3. In § 211.9, footnote 5, remove the citation ''12 U.S.C. 616'' and add in its place ''12 U.S.C. 615''.

PART 265—RULES REGARDING DELEGATION OF AUTHORITY

1. Section 265.5(d)(3) is revised to read as follows:

§ 265.5 Functions delegated to Secretary of the Board.

* * * * *

(d) * * *

(3) *Investments in Edge and Agreement Corporations.* To approve an application by a member bank to invest more than 10 percent of capital and surplus in Edge and agreement corporation subsidiaries, provided that:

(i) The member bank's total investment, including the retained earnings of the Edge and agreement corporation subsidiaries, does not exceed 20 percent of the bank's capital and surplus or would not exceed that level as a result of the proposal; and

(ii) The proposal raises no significant policy or supervisory issues.

* * * * *

2. Section 265.11(d)(11) is revised to read as follows:

§ 265.11 Functions delegated to Federal Reserve Banks.

* * * * *

(d) * * *

(11) *Investments in Edge and agreement Corporation subsidiaries.* To approve an application by a member bank to invest more than 10 percent of capital and surplus in Edge and agreement corporation subsidiaries, provided that:

(i) The member bank's total investment, including the retained earnings of the Edge and agreement corporation subsidiaries, does not exceed 20 percent of the bank's capital and surplus or would not exceed that level as a result of the proposal; and

(ii) The proposal raises no significant policy or supervisory issues.

* * * * *

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, November 16, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–29177 Filed 11–21–01; 8:45 am]

BILLING CODE 6210–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 722 and 742

Regulatory Flexibility Program

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board is issuing a final rule that will permit credit unions with advanced levels of net worth and consistently strong supervisory examination ratings to be exempt, in whole or in part, from certain NCUA regulations. The NCUA Board is also issuing a final amendment to the appraisal regulation to increase the dollar threshold from $100,000 to $250,000 for when an appraisal is required. This final rule and final amendment will reduce regulatory burden.

DATES: The rule is effective March 1, 2002.

FOR FURTHER INFORMATION CONTACT: Michael J. McKenna, Senior Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, Virginia 22314 or telephone (703) 518–6540; or Lynn K. Markgraf, Program Officer, Office of Examination and Insurance, 1775 Duke Street, Alexandria, Virginia, or telephone (703) 518–6360.

SUPPLEMENTARY INFORMATION: On March 16, 2000, the NCUA Board issued an advance notice of proposed rulemaking (ANPR) on a regulatory flexibility and exemption (RegFlex) program with a sixty-day comment period. 65 FR 15275 (March 22, 2000). The Board received seventy-four comments on the RegFlex concept. After reviewing the issues addressed by the commenters, the Board issued a Notice of Proposed Rulemaking (NPR) on March 8, 2001. 66 FR 15055 (March 15, 2001). Although the Board actually received over 1400 letters or e-mail messages, NCUA staff credited multiple comment letters from the same credit union as one comment, for a total of 1304 comments on the proposed rule. Comments were received from 551 federal credit unions, 267 state-chartered credit unions, 438 credit union volunteers or members, 33 leagues, six national credit union trade associations, four realtors and associations, one bank trade association, one appraisal association, one insurance company, one law firm, and one construction company.

In general, 1297 commenters supported the proposed regulation and many commenters supported the proposal as written. Many supporters encourage the NCUA Board to provide further regulatory flexibility in the future. A number of commenters recommended some changes to the proposed rule. Many commenters commended the Board for its bold initiative and most of them believe this regulatory approach will reduce regulatory burden and provide greater flexibility for those credit unions that have demonstrated a track record of safe and sound operations.

Seventy-nine commenters believe that RegFlex credit unions will have a competitive advantage and fifty-eight of these commenters believe that well-managed credit unions deserve this advantage. Thirty-six commenters stated that RegFlex credit unions would not have a competitive advantage.

Regarding risk to the National Credit Union Share Insurance Fund (NCUSIF), 184 commenters stated that the adoption of this proposal will not significantly increase risk. Most of these commenters believe no increase in risk will occur because healthy credit unions have the ability to manage any increased safety and soundness concerns. Two commenters believe the proposal will increase risk. Many commenters believe the regulation will encourage credit unions to become stronger financial institutions.

Discussion

RegFlex Criteria

The first criterion for eligibility under this proposal, is that credit unions must have received a composite CAMEL code 1 or code 2 for two consecutive exams. The second criterion is that a credit union must have a net worth ratio of nine percent or greater, and be well-capitalized under NCUA's prompt corrective action regulations. 12 CFR Part 702. The NCUA Board believed the proposed criteria were generally sound and did not propose that a CAMEL 1 or 2 in management needs to be part of the criteria. One hundred and five commenters specifically supported the eligibility requirements as proposed. Twenty-two commenters specifically agreed with the NCUA Board that there should not be a separate management component for RegFlex eligibility. A few commenters stated that a credit union should have a 1 or 2 in management to be eligible for RegFlex.

A few commenters suggested different eligibility requirements to obtain the benefits of RegFlex. One of these commenters requested the Board not only look at the net worth and CAMEL ratings of credit unions, but also look to how well they are serving their members and whether those members are satisfied. Almost all of the other commenters' suggestions retained some of the Board's proposal of either a CAMEL component or net worth ratios. While the Board agrees that service to members and member satisfaction are important issues for credit unions, these are not generally considered to be safety and soundness issues, and would not be easily measured criteria for purposes of RegFlex. The Board continues to believe that CAMEL ratings and net worth ratios are the best measures of how well a credit union is managed and how much risk it presents to the NCUSIF and the credit union system. That is, consistent with safety and soundness concerns, credit unions with advanced levels of net worth and consistently strong supervisory examination ratings have earned exemptions from certain NCUA Regulations.

CAMEL Rating

Thirty-two commenters stated that CAMEL ratings should not be used to determine eligibility because they can be used unfairly by examiners to keep credit unions out of the program. Many of these commenters believe that the CAMEL rating is arbitrary and

subjective to the individual examiner. Three commenters suggested a different time period for maintaining the CAMEL component. Thirteen commenters suggested using call report data and financial statements instead of a CAMEL rating. As discussed above, the Board is retaining the requirement that a credit union must have received a composite CAMEL code 1 or code 2 for two consecutive exams. The Board understands the commenters' concerns that a credit union may be unfairly kept out of the program. However, the application process should help alleviate some of these concerns because a credit union that lacks the required CAMEL rating can still apply to be part of the program if it has sufficient net worth. In addition, if credit union management believes its CAMEL rating is being manipulated, it should ask the regional director to review the issue.

Net Worth Requirement

Regarding the net worth requirement, 485 commenters believe the nine percent net worth requirement should be decreased. Four hundred and fifty-six of these commenters stated the net worth requirement should be seven percent and sixteen of these commenters stated that the net worth requirement should be eight percent. The remaining commenters offered varying numbers. As discussed above, the Board is retaining the requirement that a credit union must have a net worth ratio of nine percent or greater, and be well-capitalized under NCUA's prompt corrective action regulations. The ability to build capital, which is demonstrated by the cushion of 200 basis points, represents a significant decrease in risk to both the credit union and the NCUSIF. Some of the reasons for this 200 basis point cushion are to minimize the risk of engaging in the expanded authority permitted by the RegFlex program as well as to minimize PCA implications. The Board continues to believe that the 200 basis point margin provides a sufficient margin of safety for RegFlex credit unions to withstand unexpected events and normal business fluctuations.

Net Worth Requirement for Complex Credit Unions

The NCUA Board proposed a different net worth requirement for complex credit unions: Nine percent or 200 basis points over their risk based net worth (RBNW) requirements, whichever is greater. This net worth requirement is beyond the ''well-capitalized'' threshold established by prompt corrective action (PCA). The NCUA Board stated that a significant margin of safety for complex credit unions is afforded by net worth ratios exceeding general requirements, especially when combined with stable, high CAMEL ratings.

Thirty-two commenters approved of the higher standard for ''complex'' credit unions. Nineteen commenters stated that the trigger should be the same for all types of credit unions. Three commenters stated that a credit union that is 200 basis points over its net worth requirement for PCA should qualify for RegFlex, even if they do not have nine percent net worth. A few commenters suggested that the alternative measure for complex credit unions should be deleted. A few other commenters suggested different triggers for complex credit unions. One commenter stated that examiners should determine the net worth requirement for the purpose of RegFlex eligibility.

The Board continues to believe that a 200 basis point margin over the minimum level required of a non-complex credit union will provide a sufficient, but not excessive, safety cushion to keep credit unions from ''bouncing'' in and out of RegFlex eligibility. Credit unions that meet the definition of ''complex'' under PCA do so because of additional balance sheet risk. In order to provide the safety cushion and risk mitigation RegFlex contemplates, a higher net worth level is needed. Again, as with non-complex credit unions, a 200 basis point cushion over the minimum level for a complex credit union to be classified as well-capitalized is considered to be a sufficient safety cushion to keep these credit union from ''bouncing'' in and out of RegFlex eligibility.

The NCUA Board has made some minor modifications in the language in the final rule in §§ 742.1 and 742.2 to make it consistent with the language in NCUA's prompt corrective action regulations.

RegFlex Process

The NCUA Board proposed an automatic exemption for credit unions meeting the eligibility requirements. The Board noted that, as credit unions become eligible for RegFlex, NCUA will notify credit unions of their eligibility, generally, during the examination process. Four hundred and sixty-one commenters believe the exemption should be automatic for credit unions that qualify, just as the Board proposed. A few commenters believe approval should be automatic with a notification to NCUA by the credit union. A few commenters stated that the process should not be automatic and that the credit union should apply to NCUA for approval. The NCUA Board believes that an automatic exemption is consistent with the spirit of the RegFlex concept and will not require any application for these credit unions meeting the criteria. As credit unions become eligible for RegFlex, NCUA will notify credit unions of their eligibility, generally, during the examination process.

The NCUA Board also proposed an application process for credit unions that meet only one of the two stated criteria to allow more credit unions to have RegFlex authority while maintaining the safety and soundness considerations that are fundamental to the program. The NCUA Board proposed that if a credit union is a CAMEL 3 (or CAMEL 1 or 2 for less than two consecutive cycles) with a net worth in excess of nine percent or if the credit union is a CAMEL 1 or 2 with a net worth under nine percent (or if complex, its risk based net worth level is lower than nine percent or 200 basis points over their risk based net worth requirements), a credit union can apply to the regional director for a RegFlex designation.

Twenty-five commenters supported an application process for credit unions that meet only one of the two eligibility criteria. A few of these commenters would only allow credit unions that meet the CAMEL criteria to use the application process. These commenters believe that the CAMEL component is a better indicator of safety and soundness than the net worth criteria. Two commenters did not support the application process. A number of commenters that addressed this issue requested that the rule state the criteria the regional director will consider when making this determination.

The NCUA Board continues to believe that the RegFlex authority should be extended to as many credit unions as possible while maintaining the safety and soundness considerations that are fundamental to the program. Therefore, the NCUA Board is retaining in the final rule the application process described above. The regional director will review the application in relation to the criteria that was not met for RegFlex, that is, net worth level or safety and soundness issues that resulted in a lower CAMEL rating. In the case of a credit union not meeting the new worth level, the regional director will review past, present and projected future performance, from both a managerial and financial perspective, to determine RegFlex approval. For those credit unions that meet net worth levels but not CAMEL rating requirements, the regional director's review will focus on the magnitude and resolution of the

issues that resulted in the lower CAMEL rating.

The proposal stated that a regional director, in his or her sole discretion, for substantive and documented safety and soundness reasons, would be able to revoke the RegFlex authority in whole or in part at any time and without advance notice. In such cases, a credit union would be able to appeal the determination to NCUA's Supervisory Review Committee within 60 days of the regional director's determination. One hundred and seven commenters support the regional directors' ability to revoke a RegFlex designation. A few of these commenters suggested allowing a grace period for a credit union if it has minimal deviation from the eligibility requirements for one or more periods. If a credit union falls below the net worth eligibility requirements for a projected short period of time, the credit union should apply for a ''grace period'' and the regional director will make a determination on whether to revoke, in whole or in part, the RegFlex authority. The regional director will review the continued RegFlex eligibility in the same manner as stated above for the application process. Assessing the issues that cause the deviation will eliminate credit unions operating near the minimum net worth requirements from making multiple requests to continue RegFlex activities. If a credit union's CAMEL rating is lowered so that the credit union meets neither eligibility requirement, the regional director will revoke the RegFlex designation.

Sixty-four commenters do not approve of the regional director having sole discretion to revoke a RegFlex designation. A few commenters believe that a regional director should only have the authority to revoke a designation if a credit union no longer meets the RegFlex eligibility criteria. A few commenters suggested that only the central office should be able to revoke the RegFlex designation. The NCUA Board believes a regional director's authority to revoke the exemption is integral to success of the program. External events, as well as internal events, can produce a dramatic change in a credit union's financial condition in a matter of months. The regional director should have the discretion to act quickly in regard to RegFlex eligibility to maintain the financial health of a credit union when certain events or trends exist. The Board also believes that the regional director will be able to make a more informed and expedited decision than central office staff. Therefore, the final rule retains the ability of the regional director to revoke the RegFlex designation.

Most of the commenters, whether for or against the regional directors' discretion, support the proposed rule's requirement that the regional director first notify the credit union of the revocation and provide the credit union with appeal rights. The NCUA Board is retaining the appeal process outlined in the proposed rule. NCUA is in the process of revising IRPS 95–1 on the Supervisory Review Committee to include RegFlex issues as an appeal that the Committee is authorized to address.

Five commenters agreed with the NCUA Board that, if a credit union loses RegFlex eligibility, its past actions will be grandfathered. Therefore, the NCUA Board is retaining in the final rule the express statement that, if a credit union loses its RegFlex eligibility, its past actions are grandfathered and no divesture is required. However, this does not diminish NCUA's authority to require a credit union to divest its investments or assets for substantive safety and soundness reasons.

(1) Section 701.36—FCU Ownership of Fixed Assets

The NCUA Board proposed including sections of the fixed asset rule, including the five percent limitation, in the RegFlex rule. In the proposal, the NCUA Board encouraged, but did not require, that a RegFlex credit union incorporate into its business plan the fixed asset limit it plans to establish. Four hundred and fifty-one commenters supported the Board's inclusion of the fixed asset rule in RegFlex. Many of these commenters stated a credit union's board of directors should set the fixed asset limit. Fifteen commenters stated that all credit unions should be exempt from the fixed asset rule. Three commenters did not believe the fixed asset rule should be part of RegFlex. A few commenters requested that RegFlex credit unions be exempt from all provisions of the fixed asset rule. The NCUA Board believes the 5% limitation on fixed assets should be eliminated for credit unions that qualify for RegFlex. However, the NCUA Board encourages the board of directors of each RegFlex credit union to establish a fixed asset limitation and incorporate that limit into its written business plan.

While the NCUA Board noted that an exemption from some of the restrictions on purchasing a building and leasing a portion of the property would also be lifted under RegFlex, it stated this would not authorize a credit union to engage in long-term commercial leasing. For safety and soundness and legal reasons, the NCUA Board stated that a credit union still must comply with § 701.36(d) of the fixed asset rule and have a plan to use the property for its own operation. Seven commenters specifically endorsed federal credit unions complying with § 701.36(d). Thirty-five commenters would exempt RegFlex credit unions from this section. However, for legal and safety and soundness reasons, the Board believes that RegFlex credit unions should abide by this provision and have a plan to use the property for its own operation because federal credit unions do not generally have the authority to engage in commercial leasing. One commenter stated that NCUA should expand § 701.36(d) from a three-year to a five-year period for partial utilization of real property for RegFlex credit unions. The agency is evaluating this suggestion and may consider such an expansion when the fixed asset rule is next reviewed and revised.

The NCUA Board stated in the preamble to the proposed rule that RegFlex credit unions should also comply with the conflict of interest provision in § 701.36(e) of the rule. The Board stated that this conflict of interest provision is sound, consistent with the Federal Credit Union Bylaws, and already offers more flexibility than other conflict of interest provisions in NCUA's regulations. Only two commenters addressed this issue and approved of RegFlex credit unions continuing to follow the conflict of interest section of the fixed asset rule. The NCUA Board is retaining in the final rule that RegFlex credit unions comply with the conflict of interest provision in the fixed asset rule.

Finally, the NCUA Board requested comment on whether the fixed asset rule, itself, should be structured differently so that there would be a tiered limit on fixed assets. A few commenters requested more flexibility on the limit in the fixed asset rule. Seventeen commenters supported a tiered structure based on a percentage of net worth. Two commenters opposed a tiered structure. A few commenters provided different methods for calculating a fixed asset limit. The NCUA Board is committed to revising the fixed asset rule and will consider the use of some type of a tiered structure, such as the one used by the Office of Thrift Supervision, when the rule is revised.

(2) Part 703—Investment and Deposit Activities

The NCUA Board proposed lifting certain investment requirements for RegFlex eligible credit unions. Three hundred and one commenters supported including the proposed sections of the investment rule in

RegFlex. Eight of these supporters stated that NCUA needed to reduce investment requirements further for those credit unions with acceptable capital ratio levels. A few commenters believe other provisions of the investment regulation should be considered, but they did not make specific recommendations. One commenter believes that the investment changes should apply to all credit unions.

In response to these comments, the NCUA Board directed the Office of Investment Services and the Office of Examination and Insurance to review part 703 to determine if regulatory relief can be provided to all credit unions in the context of amending part 703. As a result of this review, the NCUA Board issued an Advanced Notice of Proposed Rulemaking (ANPR) in October of this year, requesting comment from credit unions on expanding selected sections of part 703.

One commenter believes RegFlex credit unions should be able to make any investments that banks may. Federal credit unions do not have the same statutory investment authority as banks so the Board cannot adopt this suggestion. *See* 12 U.S.C. 1757(15). One commenter would not include the investment regulation in RegFlex because the commenter perceived an increase in risk. Three commenters stated they did not approve of expanding investment powers. The NCUA Board recognizes these concerns but believes institutions meeting the RegFlex criteria can manage the additional risk.

Section 703.90(c) requires quarterly stress testing (300 basis point shock) of individual complex securities if the total sum of complex securities, as defined by the investment regulation, exceeds net capital. For those credit unions that measure the impact of interest rate changes on their entire balance sheet as part of their asset liability management programs, the NCUA Board proposed waiving this regulatory requirement for RegFlex credit unions. The NCUA Board also stated that RegFlex credit unions should continue to measure, at least quarterly, the impact of a sustained, parallel shift in interest rates of plus and minus 300 basis points on their entire balance sheet as part of their asset liability management monitoring. Fifty-nine commenters would waive the 300 point basis point shock test for RegFlex credit unions. Twelve commenters opposed waiving the quarterly stress testing for RegFlex credit unions. The NCUA Board has decided to include this investment provision in the final regulation because it does not pose a significant adverse effect for RegFlex credit unions. This exemption does not eliminate stress testing, rather it reduces duplicative reporting burden for those institutions that have a risk management process that measures the impact of interest rate changes on the entire balance sheet.

Section 703.40(c)(6) limits the discretionary delegation of investments to third parties to 100% of net capital. NCUA proposed waiving the 100% limitation and permitting RegFlex credit unions to set their own limit in a policy adopted by their boards of directors. Eighty-seven commenters believe it is appropriate for NCUA to waive or modify the 100% limitation on discretionary delegation of investments and allow the credit union to set a limit via board policy. Five commenters did not support waiving the 100% limitation on discretionary delegation of investments for RegFlex eligible credit unions. The NCUA Board has decided to include this investment provision in the final regulation because it offers expanded investment portfolio management options for RegFlex institutions and it would not have a significant adverse impact on safety and soundness.

Section 703.110(d) limits zero coupon investments to under ten years from settlement date. The NCUA Board proposed removing this limitation for RegFlex credit unions. Twelve commenters specifically supported the exemption; seven commenters specifically did not. The NCUA Board has decided to include this investment provision in the final regulation because it would not have a significant adverse impact on safety and soundness and would increase potential yield when part of a managed ALM.

The NCUA Board had previously decided not to include § 703.110, which prohibits stripped, mortgage-backed securities, residual interests in CMOs/REMICS, mortgage servicing tights, commercial mortgage-related securities, or small business related securities. Nevertheless, a number of commenters discussed this section. Thirty-two commenters stated NCUA should permit RegFlex credit unions to make these type of investments. Thirteen commenters believe stripped mortgage-backed securities and residual interests in CMOs/REMICs are not viable investments for credit unions. Twelve commenters stated these are high risk investments and suggested that perhaps a percentage of total investment could be allowed if credit unions measure risk adequately. Because of the risk associated with these types of investments, the NCUA Board has decided not to incorporate it into the final regulation. However, as discussed earlier, comments on these investment activities are requested in the ANPR on part 703.

Five commenters requested investments in commercial paper for RegFlex credit unions. One commenter would permit natural person credit unions the same investment powers as corporate credit unions. One commenter believes NCUA should allow credit unions to purchase principal-only stripped mortgage-based securities to hedge interest rate risk as the value of the security moves positively to a rate increase. Section 120(a) of the Federal Credit Union Act authorizes the NCUA Board to provide expanded investment authority for corporate credit unions by regulation. This statutory flexibility does not exist for natural person credit unions. The ANPR on part 703 requested comments on authorizing principal-only strips as a vehicle to hedge interest rate risk.

(3) Section 701.25—Charitable Donations

The current rule limits recipients of charitable donations to organizations located in or conducting activities in a community in which the federal credit union has a place of business. Furthermore, the board of directors must approve charitable contributions, and the approval must be based on a determination by the board of directors that the contributions are in the best interests of the federal credit union and are reasonable given the size and financial condition of the federal credit union. The NCUA Board asked whether credit unions meeting the RegFlex criteria should be completely exempt from the requirements of this regulation. Eighty-three commenters stated that the entire charitable donations regulation should be part of RegFlex. One hundred and forty-four commenters believe the charitable donations regulation should be eliminated for all federal credit unions. Three commenters would not include charitable donations as part of RegFlex.

The NCUA Board is convinced that credit unions qualifying for RegFlex have proven their track record of sound management and should be exempt from the charitable donations regulation. However, the Board is not convinced that this exemption should apply to all credit unions. The donation of a credit union's members' money to an outside party is a highly sensitive issue. The Board believes the requirements in the current regulation are critical for nonqualifying credit unions to ensure that the interests of the credit union's members are protected

and that conflicts of interest are avoided.

(4) Sections 701.32(b) and (c)—Payment on Shares by Public Unit and Nonmembers

The current regulation limits the maximum amount of all public unit and nonmember shares to 20% of total shares of a federal credit union or $1.5 million, whichever is greater. The NCUA Board proposed that these provisions be part of the RegFlex rule. Two hundred and six commenters supported including the proposed provisions on public unit and nonmember accounts in the final rule. Seven commenters would not include these provisions as part of RegFlex. Eight commenters stated that low-income credit unions should be exempt from the limits on nonmember shares. One commenter stated that RegFlex credit unions should be exempt from all of the provisions of § 701.32. Twenty-one commenters stated this exemption should apply to all credit unions.

A number of commenters stated this regulation is unnecessary because of PCA. While PCA may serve to discourage excessively rapid asset growth in a credit union, it does not mitigate the additional risks that may be presented by nonmember shares. These accounts frequently are attracted by offering higher than normal dividend rates and are characteristically more volatile than core member shares. This additional volatility can pose asset-liability management concerns and liquidity concerns. The NCUA Board has not been provided any convincing rational for exempting all federal credit unions from these provisions and has incorporated it in the final rule.

Two commenters stated this provision should also apply to state-chartered credit unions due to the language in § 741.204. The NCUA Board agrees with this comment. If a state-chartered credit union meets the RegFlex criteria, then the credit union need not comply with § 701.32(b) and (c). A state-chartered credit union that only meets one of the two criteria may also avail itself of the application process.

(5) Section 701.23—Purchase, Sale and Pledge of Eligible Obligations

The NCUA Board requested comment on whether to permit credit unions that meet the RegFlex criteria to purchase any auto loan, credit card loan, member business loan, student loan, or mortgage loan from any other credit union as long as they are loans the purchasing credit union is empowered to grant. The only limitation to this authority is the statutory limitation regarding the purchase of eligible obligations from liquidating credit unions. One hundred and sixty-three commenters supported expanding the authority for the purchase and sale of eligible obligations. Some of the commenters believe this provision would help the safety and soundness of the credit union system. Seven commenters suggested this section apply to all federal credit unions.

One commenter stated that, due to the NCUSIF nexus in § 741.8, state-chartered credit unions must also be granted this additional authority. The NCUA Board is cognizant that it failed to state clearly that RegFlex credit unions may purchase eligible obligations from federally insured credit unions. The final rule has been amended to make this distinction clear. Section 741.8 does not preempt a state's rule that grants the same authority as this RegFlex provision.

One commenter recommended that credit unions be able to purchase member loans from other financial institutions and business entities but was not able to provide a compelling legal basis for this extension of authority. One commenter objected to the inclusion of this section and stated that allowing federal credit unions to hold these loans in their portfolio is contrary to NCUA's historical position. The authority for this provision is in section 107(14) of the Federal Credit Union Act. The legal analysis for including this provision in RegFlex was addressed in the preamble to the proposed rule and need not be repeated here. 66 FR 15055, 15059 (March 15, 2001). The NCUA Board believes this authority expands the liquidity options for credit unions and enhances the safety and soundness of the credit union system. Therefore, the NCUA Board is incorporating this authority into the final regulation, with the only limitation being the statutory limitation regarding the purchase of eligible obligation from liquidating credit unions.

Comments on Other Regulations

The NCUA Board requested comment on whether any other regulation should be part of the RegFlex program. Numerous comments were received on various regulations, most of which the Board previously stated would not be part of RegFlex or are statutorily required.

Mortgage Lending—Section 701.21(f) and (g)

One hundred and seventy commenters recommended easing regulatory limits or ''examiner guidelines'' limiting mortgage lending for RegFlex credit unions. These commenters mistakenly believe there are examiner guidelines or a regulatory limit on how many mortgages a credit union may make. Five commenters asked that mortgage lending be liberalized, but did not specify how this should be accomplished. The agency will continue to review its mortgage lending regulation to determine if it can reduce regulatory burden. One hundred and one commenters requested that RegFlex credit unions be exempt from loan maturity limits. One commenter suggested that RegFlex credit unions have 30 years to finance the purchase of vacation or rental properties. One commenter believes RegFlex credit unions should have a 30-year maturity on home improvement and home equity loans. Most of NCUA's loan maturity limits are statutory but the agency will continue to review § 701.21(f) to determine if there is a need to expand the 20-year maturity limit for those specified types of loans.

Leasing—Part 714

In the proposal, the NCUA Board stated that the leasing regulation is not currently a good candidate for RegFlex because of safety and soundness concerns. In any case, seventy-four commenters recommended including the leasing regulation as part of RegFlex, but did not specify whether it should include the whole regulation or simply certain provisions. Six commenters requested an exemption from the 25% residual interest requirement imposed by § 714.4. Five commenters would not include leasing in RegFlex. One commenter requested that NCUA exempt all credit unions from the leasing regulation. The NCUA Board is not persuaded that the leasing regulation should be part of RegFlex. The NCUA Board has safety and soundness concerns regarding leasing and has not been provided any convincing rationale on why the leasing regulation is unduly burdensome.

Incidental Powers—Part 721

The NCUA Board stated that it did not believe the new incidental powers activities regulation should be part of RegFlex. Six commenters stated that RegFlex credit unions should have greater latitude with their incidental powers. One commenter stated that incidental powers should not be part of RegFlex. The NCUA Board issued a final rule on incidental powers in July that expands a credit union's incidental powers activities and is applicable to all federal credit unions.

Interest Rate Ceiling—Section 701.21(c)(7)

One commenter requested that the NCUA Board increase the interest rate ceiling for RegFlex credit unions. NCUA is statutorily required to review its interest rate ceiling every 18 months if the ceiling is above 15%. The NCUA Board does not believe RegFlex credit unions should have a higher interest rate ceiling than the current 18%.

CUSO Regulation—Part 712

One commenter recommended that NCUA should exempt RegFlex credit unions from unspecified provisions of the CUSO regulation. The NCUA Board is not including the regulation in RegFlex because it was updated in July of this year and it received no specific recommendation. The Board wishes to note that the 1% investment and lending limits are statutory. *See* 12 U.S.C. 1757(5)(D) and (7)(I).

Member Business Loans—Part 723

One commenter recommended that NCUA exclude the member business loan regulation from RegFlex. Thirty-four commenters requested exemptions from member business loan requirements that are not statutory in nature. Seven other commenters requested more flexibility in member business loans. Seventy commenters stated RegFlex credit unions should be exempt from the loan-to-value requirements in the member business loan regulation. One commenter requested an exemption from the staff experience requirement in the member business loan regulation. Four commenters would lift the statutory cap on member business loans for RegFlex credit unions. Two commenters requested that RegFlex credit unions have the ability to offer unsecured business loans that are not credit cards or lines of credit up to a present limit of $50,000. One commenter requested the amount of the aggregate loan limit on business loans to one individual or group should be increased to 25% of net worth for RegFlex credit unions. The NCUA Board does not believe the member business loan regulation is a good candidate for RegFlex because of statutory requirements and safety and soundness concerns. *See* 12 U.S.C. 1757a. However, as a part of the agency's ongoing regulatory review process, the entire member business regulation is scheduled for review in 2003. The NCUA Board will continue with its efforts to reduce, where appropriate, regulatory burden.

Fidelity Bond Coverage—Part 713

Four commenters stated RegFlex credit unions should be exempt from unidentified provisions of part 713 on fidelity bond coverage. The NCUA Board believes this regulation is minimally burdensome for credit unions and, due to safety and soundness concerns, will not be part of RegFlex.

Field of Membership Issues

In the proposal, the NCUA Board stated that field of membership issues should not be part of RegFlex. Nevertheless, numerous commenters addressed this issue. Sixteen commenters did not believe field of membership issues should be part of RegFlex. One commenter stated field of membership issues should be part of RegFlex.

One hundred and forty-eight commenters supported freezing the asset base for purposes of calculating the operating fee as an incentive for expanding into the low-income area. Four commenters disagreed with this provision being part of RegFlex. One hundred and twenty commenters supported the use of incentives to encourage credit unions to expand into low-income or underserved communities. Four commenters did not approve of any incentives for credit unions to add underserved areas.

Last year, the NCUA Board issued final amendments to NCUA's Chartering Manual that addressed the addition of underserved areas. Although the NCUA Board deferred any action regarding incentives, it did streamline the application process. As a result, over one hundred and twenty-seven federal credit unions have added underserved areas this year. It appears that no incentives are warranted since credit unions are rapidly expanding into underserved areas. The Board will continue to monitor this issue and, if the increase in service to underserved areas begins to diminish significantly, it will review the issue again.

Examination Issues

Although the NCUA Board did not request comment on changes to NCUA's supervision and examination program for credit unions meeting the RegFlex criteria, many commenters addressed this issue. Five hundred and one commenters stated that a different exam cycle or more favorable examination treatment should be offered to RegFlex credit unions. Many of these commenters requested a streamlined examination process for RegFlex credit unions. Most of these commenters suggested an 18 to 24 month cycle. Many of these commenters also stated that outside auditors should perform audits in lieu of on-site examinations to save time and avoid duplication. Three commenters stated that RegFlex credit unions should not have more favorable treatment than other credit unions. The NCUA Board recently adopted a risk-based examination scheduling policy, that will result in many credit unions being examined twice over a three-year period. The agency's intent is to move toward a more risk-focused examination approach to place greater reliance on outside audits. This approach, however, will not relieve NCUA of its responsibility to evaluate safety and soundness. The role of an audit is to evaluate the adequacy of internal controls and to attest to the fairness of financial statement presentation, but not to evaluate risk to the NCUSIF. The NCUA Board will continue to review the examination process to determine if it can be further streamlined and improved.

Four commenters suggested that NCUA should revise peer comparisons for RegFlex credit unions. Four other commenters stated that NCUA should eliminate peer comparisons for RegFlex credit unions. Two commenters were not in favor of eliminating peer comparisons and do not believe that delinquency and charge-off ratios should be less important to examiners. NCUA provides peer comparisons primarily for use by credit union management. Generally, the agency finds that credit unions appreciate receiving this information and, in fact, some have requested that NCUA provide a more detailed presentation of the data. The peer information is used by NCUA examiners as a frame of reference, rather than a determination of a CAMEL rating. Two commenters requested more flexibility on delinquency and charge-offs for RegFlex credit unions. One commenter perceives a tendency for examiners to recommend that credit unions develop written policy statements to replace current documented operating procedures. Since these comments primarily relate to examination issues affecting all credit unions, they will be addressed separately from this rule. NCUA is currently reviewing these issues and may incorporate some of these ideas in the revised examiners guide.

Prompt Corrective Action—Part 702

One hundred and fifty-three commenters believe NCUA should grant RegFlex credit unions more favorable treatment under PCA. The basic net worth criteria contained in the PCA were established by Congress, and

NCUA does not have the ability to change them. More importantly, to be eligible for RegFlex, a credit union's net worth must exceed, by 200 basis points, the minimum level for it to be well capitalized under PCA. By virtue of being well capitalized, the credit union is not affected by PCA, and there is no more favorable treatment that could be offered under PCA.

State Charters

Twenty-two commenters stated that NCUA should expand the rules to make RegFlex applicable to state-chartered credit unions. The NCUA Board recognizes and is committed to the dual chartering system. Likewise, as the regulator of federal credit unions, the NCUA Board is committed to reducing regulatory burden, where appropriate, on federal credit unions. On those occasions when a regulation applies to state-chartered credit the NCUA Board will expand RegFlex to them.

Section 722.3(a)(1)—Proposed Amendment to the Appraisal Regulation

NCUA's current appraisal regulation is more restrictive than the regulations of other financial institution regulators. Because experience has demonstrated that most credit unions are able to manage a higher degree of risk in making loans without an appraisal, the NCUA Board proposed an amendment to § 722.3(a)(2) to increase the threshold for an appraisal from $100,000 to $250,000. The NCUA Board also proposed to increase the threshold for an appraisal for a member business loan to $250,000 if it involves real estate. The increase would be consistent with the regulatory provisions of the agencies regulating banks and thrifts. Two hundred and eighty-two commenters fully supported the proposed dollar threshold for an appraisal. Twenty commenters objected to increasing the appraisal threshold. One commenter opposed increasing the threshold for business lending because this commenter believes this type of lending is riskier. One commenter suggested that NCUA modernize appraisal requirements for agricultural lending.

The NCUA Board has not been persuaded that the increase in the appraisal threshold would significantly increase safety and soundness concerns so the proposed amendment is adopted in the final rule. Credit unions must still make reasonable determinations of value to ensure compliance with loan-to-value requirements. Section 722.3(d) of the appraisal rule requires that a real estate related transaction under the dollar threshold be supported by a written estimate of market value performed by an independent, qualified, and experienced individual. In addition, § 722.3(e) allows NCUA to require an appraisal whenever necessary to address safety and soundness concerns. These two sections of the appraisal rule mitigate any potential safety and soundness concerns raised by increasing the dollar threshold.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any regulation may have on a substantial number of small entities (primarily those under $1 million in assets). The NCUA Board has determined and certifies that the final rule will not have a significant economic impact on a substantial number of small credit unions. The reason for this determination is that the final rule reduces regulatory burden. Accordingly, the NCUA Board has determined that a Regulatory Flexibility Analysis is not required.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by section 551 of the Administrative Procedures Act. 5 U.S.C. 551. The Office of Management and Budget has determined that this is not a major rule.

Paperwork Reduction Act

The application requirements in part 742 have been submitted to the Office of Management and Budget. Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB Number. The control number will be displayed in the table at 12 CFR part 795.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their regulatory actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. One section of this final rule will lift a regulatory requirement for some federally-insured state-chartered credit unions. However, this final rule will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that the rule does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act of 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Pub. L. 105–277, 112 Stat. 26821 (1998).

List of Subjects

12 CFR Part 722

Credit unions, Mortgages, Reporting and recordkeeping requirements.

12 CFR Part 742

Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on November 15, 2001.

Becky Baker,

Secretary of the Board.

For the reasons stated in the preamble, 12 CFR chapter VII is amended as follows:

PART 722—APPRAISALS

1. The authority citation for part 722 continues to read as follows:

Authority: 12 U.S.C 1766, 1789 and 3339.

§ 722.3 [Amended]

2. Section 722.3(a)((1) is amended by replacing the number ''100,000'' with ''250,000'' and removing the words ''except if it is a business loan and then the transaction value is $50,000 or less.''

3. Add part 742 to read as follows:

PART 742—REGULATORY FLEXIBILITY PROGRAM

Sec.

Authority: 12 U.S.C 1756 and 1766.

§ 742.1 What is NCUA's Regulatory Flexibility Program?

NCUA's Regulatory Flexibility Program (RegFlex) exempts credit unions with a current net worth of nine percent (or if a credit union is subject to a risk-based net worth requirement under § 702.103 of this chapter, it must be 200 basis points over its risked based net worth level or nine percent, whichever is higher) and a CAMEL rating of 1 or 2, for two consecutive examinations, from all or part of identified NCUA regulations. The Regulatory Flexibility Program also grants eligible credit unions additional powers.

§ 742.2 How do I become eligible for the Regulatory Flexibility Program?

Eligibility is automatic as soon as the credit union meets the net worth and CAMEL criteria. If a credit union is a CAMEL 3 (or CAMEL 1 or 2 for less than two consecutive cycles) with a net worth in excess of 9 percent or if the credit union is a CAMEL 1 or 2 with a net worth under 9 percent (or if a credit union is subject to a risk-based net worth requirement under § 702.103 of this chapter, and it does not exceed 200 basis points over its risk based net worth level), it can apply to the regional director for a RegFlex designation, in whole or in part.

§ 742.3 Will NCUA notify me when I am eligible for the Regulatory Flexibility Program?

Yes. Once this rule is effective, NCUA will notify all RegFlex eligible credit unions. Subsequent notifications of eligibility will occur after an application for a RegFlex designation or as part of the examination process.

§ 742.4 From what NCUA Regulations will I be exempt?

RegFlex credit unions are exempt from the provisions of the following NCUA Regulations: § 701.25, § 701.32(b) and (c), § 701.36(a), (b) and (c), § 703.40(c)(6), § 703.90(c), and § 703.110(d) of this chapter.

§ 742.5 What additional authority will I be granted?

Notwithstanding the general limitations in § 701.23 of this chapter, RegFlex credit unions are eligible to purchase any auto loan, credit card loan, member business loan, student loan or mortgage loan from any federally insured credit union as long as the loans are loans that the purchasing credit union is empowered to grant. RegFlex credit unions are authorized to keep these loans in their portfolio. If a RegFlex credit union is purchasing the eligible obligations of a liquidating credit union, the loans purchased cannot exceed 5% of the unimpaired capital and surplus of the purchasing credit union.

§ 742.6 How can I lose my RegFlex eligibility?

Eligibility may be lost in two ways. First, the credit union no longer meets the RegFlex criteria set forth in § 742.1. When this event occurs, the credit union must cease using the additional authority granted by this rule. Second, the regional director for substantive and documented safety and soundness reasons may revoke a credit union's RegFlex authority in whole or in part. The regional director must give a credit union written notice stating the reasons for this action. The revocation is effective as soon as the regional director's determination has been received by the credit union.

§ 742.7 What is the appeal process?

A credit union has 60 days from the date of the regional director's determination to revoke a credit union's RegFlex authority (in whole or in part) to appeal the action to NCUA's Supervisory Review Committee. The regional director's determination will remain in effect unless the Supervisory Review Committee issues a different determination. If the credit union is dissatisfied with the decision of the Supervisory Review Committee, the credit union has 60 days from the issuance of this decision to appeal to the NCUA Board.

§ 742.8 If I lose my RegFlex authority, will my past actions be grandfathered?

Any action by the credit union under the RegFlex authority will be grandfathered. Any actions subsequent to losing the RegFlex authority must meet NCUA's regulatory requirements. This does not diminish NCUA's authority to require a credit union to divest its investments or assets for substantive safety and soundness reasons.

[FR Doc. 01–29152 Filed 11–21–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–SW–48–AD; Amendment 39–12508; AD 2001–19–51]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model SA341G, SA342J, and SA–360C Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) 2001–19–51, which was sent previously to all known U.S. owners and operators of Eurocopter France (ECF) Model SA341G, SA342J, and SA–360C helicopters by individual letters. This AD requires, before further flight, replacing a certain unairworthy main rotor head torsion tie bar (tie bar) with an airworthy tie bar. This AD also requires revising the limitations section of the maintenance manual by adding a life limit for certain tie bars. This AD is prompted by an accident involving an ECF Model SA341G helicopter due to the failure of a tie bar. The actions specified by this AD are intended to prevent failure of a tie bar, loss of a main rotor blade, and subsequent loss of control of the helicopter.

DATES: Effective December 10, 2001, to all persons except those persons to whom it was made immediately effective by Emergency AD 2001–19–51, issued on September 21, 2001, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before January 22, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2001–SW–48–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.*

FOR FURTHER INFORMATION CONTACT: Jim Grigg, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5490, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: On September 21, 2001, the FAA issued

Emergency AD 2001–19–51 for ECF Model SA341G, SA342J, and SA–360C helicopters which requires, before further flight, replacing certain unairworthy tie bars with airworthy tie bars. The AD also requires revising the limitations section of the maintenance manual by adding a life limit for certain tie bars and specifies that certain tie bars are not approved for installation on any helicopter. That action was prompted by an accident involving an ECF Model SA341G helicopter due to the failure of a tie bar. The ECF Model SA342J and SA–360C helicopters are equipped with tie bars identical to the one that failed on the ECF Model SA341G helicopter. Failure of a tie bar could result in loss of a main rotor blade and subsequent loss of control of the aircraft.

ECF has issued Telex Alert Nos. 01.28 and 01.38, both dated August 7, 2001, which declare certain tie bars unairworthy and impose a 20-year life limit for certain other tie bars. The Direction Generale De L'Aviation Civile (DGAC), which is the airworthiness authority for France, classified these telex alerts as mandatory and issued AD Nos. 2001–374–040(A) and 2001–375–046(A), both dated August 22, 2001, to ensure the continued airworthiness of these helicopters in France.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

Since the unsafe condition described is likely to exist or develop on other ECF Model SA341G, SA342J, and SA–360C helicopters of the same type designs, the FAA issued Emergency AD 2001–19–51 to prevent failure of a tie bar, loss of a main rotor blade, and subsequent loss of control of the helicopter. The AD requires, before further flight, replacing certain unairworthy tie bars with airworthy tie bars. The AD also requires revising the limitations section of the maintenance manual by adding a life limit for tie bars, P/N 341A31–4933–00 and 341A31–4933–01, of 20 years from initial installation on any helicopter. The existing 5,000 hours TIS life limit on those tie bars remains the same. Tie bars, P/N 341A31–4933–00 and 341A31–4933–01, are to be removed from service when either the years or hours life limit is reached, whichever occurs first. The AD also specifies that tie bars, P/N 341A31–4904–00, –01, –02, –03, and 360A31–1097–02 and –03, are not approved for installation on any helicopter. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the structural integrity and controllability of the helicopter. Therefore, the actions previously mentioned are required before further flight, and this AD must be issued immediately.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on September 21, 2001 to all known U.S. owners and operators of ECF Model SA341G, SA342J, and SA–360C helicopters. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to 14 CFR 39.13 to make it effective to all persons.

The FAA estimates that 33 helicopters of U.S. registry will be affected by this AD, that it will take approximately 8 work hours per helicopter to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $13,335 per helicopter, assuming all 3 tie bars are replaced. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $445,895 ($13,815 per helicopter).

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2001–SW–48–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2001–19–51 Eurocopter France: Amendment 39–12508. Docket No. 2001–SW–48–AD.

Applicability: Model SA341G, SA342J, and SA–360C helicopters with the following main rotor head torsion tie bar (tie bar), part number (P/N):

341A31–4904–00, –01, –02, –03;
341A31–4933–00, –01; or
360A31–1097–02, or –03;

installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required before further flight, unless accomplished previously.

To prevent failure of a tie bar, loss of a main rotor blade, and subsequent loss of control of the aircraft, accomplish the following:

(a) Remove each tie bar, P/N 341A31–4904–00, –01, –02, or –03; 360A31–1097–02 or –03, from service and replace with an airworthy tie bar, P/N 341A31–4933–00 or 341A31–4933–01.

Note 2: Eurocopter France Telex Alert Nos. 01.28 and 01.38, both dated August 7, 2001, pertain to the subject of this AD.

(b) Replace each tie bar, P/N 341A31–4933–00 or 341A31–4933–01, if 20 or more years have elapsed since initial installation on any helicopter, with an airworthy tie bar, P/N 341A31–4933–00 or 341A31–4933–01. If the date of initial installation on any helicopter cannot be determined, use the date of manufacture of the tie bar as the date of initial installation.

(c) This AD revises the limitations section of the maintenance manual by adding a life limit for tie bars, P/N 341A31–4933–00 and 341A31–4933–01, of 20 years from initial installation on any helicopter and retains the existing 5,000 hours time-in-service (TIS) life limit on those tie bars. Tie bars, P/N 341A31–4933–00 and 341A31–4933–01, are to be removed from service when either the years or hours TIS life limit is reached, whichever occurs first. Tie bars, P/N 341A31–4904–00, –01, –02, and –03, and 360A31–1097–02 and –03, are not approved for installation on any helicopter.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(e) Special flight permits will not be issued.

(f) This amendment becomes effective on December 10, 2001, to all persons except those persons to whom it was made immediately effective by Emergency AD 2001–19–51, issued September 21, 2001, which contained the requirements of this amendment.

Note 4: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France), AD's 2001–374–040(A) and 2001–375–046(A), both dated August 22, 2001.

Issued in Fort Worth, Texas, on November 9, 2001.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 01–29189 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 1

RIN 2125–AE73

Engineering Services

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: This document amends the regulation for engineering services by removing a sentence that defined expenditures for the establishment, maintenance, general administration, supervision, and other overhead of the State highway department, or other instrumentality or entity referred to in the regulation, as ineligible for Federal participation. This amendment to the regulation stems from a provision in the Transportation Equity Act for the 21st Century (TEA–21) that changed statutory requirements to allow for eligibility of administrative costs for State transportation departments.

EFFECTIVE DATE: This rule is effective December 24, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Max Inman, Federal-aid Financial Management Division, (202) 366–2853 or Mr. Steve Rochlis, Office of the Chief Counsel, (202) 366–1395, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service (202) 512–1661. Internet users may reach the Office of the Federal Register's homepage at *http://www.nara.gov/fedreg* and the Government Printing Office's database at *http://www.access.gpo.gov/nara*.

Background

Prior to the TEA–21 (Pub. L. 105–178, 112 Stat. 107 (1998), expenditures for the establishment, maintenance, general administration, supervision, and other overhead of the State highway department, or other instrumentality or entity referred to in paragraph (b) of 23 CFR 1.11, were not eligible for Federal participation. Section 302 of title 23, U.S. Code, requires a State to have a functioning transportation department as a condition for receiving Federal-aid highway funds. The FHWA has interpreted this provision, in accordance with legislative intent, to mean that the costs of operating the State transportation department were not eligible for Federal highway funds. This policy was inconsistent with general government policy issued in the Office of Management and Budget (OMB) Circular A–87 [1] which allows Federal participation in a State's indirect or overhead costs.

Section 1212 (a) of the TEA–21 amended section 302, clarifying that the requirement to maintain a suitably equipped and organized transportation department did not effect a State's eligibility to be reimbursed for costs (including costs for indirect rates).

The purpose for this statutory change was to provide for a consistent policy for cost reimbursement, specifically among Federal transportation agencies.

Therefore, the FHWA is amending the regulation for engineering services. In 23 CFR 1.11 (a), the first paragraph is amended by removing the last sentence of the paragraph, ''Expenditures for the

[1] OMB Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments, is available at the following URL: *http://www.whitehouse.gov/omb/circulars*.

establishment, maintenance, general administration, supervision, and other overhead of the State highway department, or other instrumentality or entity referred to in paragraph (b) of this section shall not be eligible for Federal participation.''

Discussion of Comments

The Federal Highway Administration did not receive any comments to the docket of the notice of proposed rulemaking published on July 26, 2000, at 65 FR 45941.

Rulemaking Analyses and Notices

This final rule makes only minor technical corrections to our existing regulation. The rule amends outdated statutory language that stems from a provision in the Transportation Equity Act for the 21st Century (TEA–21) that changed statutory requirements to allow for eligibility of administrative costs for State transportation departments. As a result of the revised statutory requirements, the FHWA is amending its regulation at 23 CFR 1.11 (a) to reflect that costs of engineering services performed by the State highway department may be eligible for Federal participation to the extent that such costs are directly attributable to specific projects.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has considered the impact of this action and has determined that it is not a significant rulemaking action within the meaning of Executive Order 12866 or significant within the meaning of the U.S. Department of Transportation regulatory policies and procedures. Since this action merely amends a regulation it is anticipated that its economic impact is minimal, therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities. Based on the evaluation and the fact that this rulemaking action merely removes an outdated regulation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This action does not impose a Federal mandate resulting in the expenditure by State, local, tribal governments, in the aggregate, or by the sector, of $100 million or more in any year. (2 U.S.C. 1531 *et seq.*)

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

We have analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This action is not economically significant and does not concern an environmental risk to health of safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 dated August 4, 1999, and it has been determined that this action does not have a substantial direct effect or sufficient federalism implications on States that would limit policymaking discretion of the States. Nothing in this document directly preempts any State law or regulation.

Executive Order 12372 (Intergovernmental Review)

Catalog of Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation of Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not create a collection of information requirement for the purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

The FHWA has analyzed this action for the purposes of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) and has determined that it would not have any effect on the quality of the environment. Therefore, an environmental impact statement is not required.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this rule under Executive Order 13175, dated November 6, 2000, and believes that the proposed action will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal law. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects under Executive Order 13211 is not required.

Regulatory Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 1

Administration, Conflicts of interest, Engineering services, Grant programs-transportation, Highways and roads, Rights-of-way.

Issued on: November 13, 2001.

Mary E. Peters,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA amends, title 23, Code of Federal Regulations, part 1, as set forth below.

PART 1—[AMENDED]

1. The authority citation for part 1 continues to read as follows:

Authority: 23 U.S.C. 315; 49 CFR 1.48 (b).

2. Revise § 1.11 (a) to read as follows:

§ 1.11 Engineering services.

(a) *Federal participation.* Costs of engineering services performed by the State highway department or any instrumentality or entity referred to in paragraph (b) of this section may be eligible for Federal participation only to the extent that such costs are directly attributable and properly allocable to specific projects.

* * * * *

[FR Doc. 01–29258 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–22–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–7105–5]

Approval and Promulgation of Implementation Plans; Texas; Revisions to General Rules and Regulations for Control of Air Pollution by Permits for New Sources and Modifications; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to receipt of adverse comments, EPA is withdrawing the direct final rule to approve revisions to Texas General Rules and Regulations for Control of Air Pollution by Permits for New Sources and Modifications. In the direct final rule published September 24, 2001 (66 FR 48796), we stated that if we received adverse comment by October 24, 2001, the direct final rule would be withdrawn and would not take effect. The EPA will address all public comments in a subsequent final rule based on the proposed rule also published on September 24, 2001 (66 FR 48850). The EPA subsequently received adverse comments on the direct final rule from Public Citizen and from Lowerre & Kelly, Attorneys at Law.

DATES: The Direct final is withdrawn as of November 23, 2001.

ADDRESSES: Copies of documents relevant to this action are available for public inspection during normal business hours at the following locations. Anyone wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

EPA, Region 6, Air Permits Section (6PD-R), 1445 Ross Avenue, Dallas, Texas 75202–2733

TNRCC, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753

FOR FURTHER INFORMATION CONTACT: Stanley M. Spruiell, Air Permits Section at (214) 665–7212 or at spruiell.stanley@epa.gov.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon Monoxide, Hydrocarbons, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 7, 2001.

Lawrence E. Starfield,

Acting Deputy Regional Administrator, Region 6.

Accordingly, the amendments to the table in § 52.2270(c) published in the **Federal Register** September 24, 2001 (66 FR 48796) is withdrawn as of November 23, 2001.

[FR Doc. 01–29100 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 130

RIN 0906–AA56

Ricky Ray Hemophilia Relief Fund Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Adoption of interim final rule as final rule with amendments.

SUMMARY: This document adopts the Ricky Ray Hemophilia Relief Fund Program interim final rule as a final rule with amendments. This final rule facilitates the petitioning process where health care history can be certified by physician assistants as well as by physicians or nurse practitioners; details the procedures by which the Secretary may resolve issues of eligibility or payment raised by a petition; ensures that payments made for the benefit of minors and other individuals who do not have the legal capacity to receive the payments are used for their benefit; and allows additional time for petitioners who are having difficulty obtaining needed medical or legal documentation to complete their petitions.

DATES: The regulations published on May 31, 2000 (65 FR 34860), were effective on July 31, 2000, and the amendments made in this final rule are effective November 23, 2001.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Program Director, Bureau of Health Professions, Health Resources and Services Administration, (301) 443–2330.

SUPPLEMENTARY INFORMATION:

Background

The Ricky Ray Hemophilia Relief Fund Act of 1998 (Public Law 105–369) established the Ricky Ray Hemophilia Relief Fund Program to provide compassionate payments to certain individuals with blood-clotting disorders, such as hemophilia, who were treated with antihemophilic factor between July 1, 1982, and December 31, 1987 and contracted HIV. The Act also provides for payments to certain persons who contracted HIV from the foregoing individuals. The spouse or former spouse of such an individual, who acquired HIV from that individual is eligible for payment, as are children who acquired HIV through perinatal transmission from an eligible parent. In addition to these individuals, certain survivors also are eligible. A lawful spouse is eligible for the payment; if there is no surviving spouse, the payment is to be made in equal shares to all children of the eligible individual. If there are no surviving spouse or children, the parents of the eligible individual will receive the payment. If none of these individuals is living, the money will remain in the Fund. There is no provision for payment to be made to an estate or to any individual beyond those explicitly mentioned in the Act.

In order to receive a payment, either the eligible individual, or someone on behalf of the eligible individual, must file a petition for payment with sufficient documentation to prove that he or she meets the requirements of the statute.

Congress appropriated $75 million to support the Ricky Ray Hemophilia Relief Fund Program during Fiscal Year (FY) 2000. As a result, we began issuing compassionate payments to eligible individuals in August 2000, in accordance with the procedures prescribed in the interim final rule. Congress has now passed an omnibus appropriations bill for FY 2001 that includes $580 million for the Ricky Ray Program. The Department anticipates that the combined total of $655 million for FY 2000 and 2001 is sufficient to make compassionate payments on all eligible petitions.

An interim final rule was published in the **Federal Register** on May 31, 2000 (65 FR 34860), to establish procedures and requirements for medical/legal documentation required to prove eligibility for individuals, a mechanism for providing compassionate payments to eligible individuals under the statute,

a reconsideration process, and to seek public comment on these provisions.

Discussion of Comments

The public comment period ended on June 30, 2000. The Department received a total of 19 public comments. Fourteen were from potential petitioners and other individuals; four were from hemophilia and HIV advocacy groups; and one was from a professional association. The issues raised and the Department's responses appear below.

A. The Petitioning Process

One commenter expressed concern that individuals might seek a competitive edge in the random selection process by filing multiple identical petitions. The commenter urged us to establish specific, fixed penalties for those individuals, such as consolidating the petitions under the highest randomly-assigned number.

The Department agrees that multiple filings of identical petitions was a possible area of abuse in the petition process. In addition, the submission of multiple copies of identical petitions would cause a significant increase in administrative costs and hinder our ability to make payments on approved petitions in a timely fashion. Accordingly, we instituted a policy that if a petitioner submitted multiple identical petitions, all such petitions would be consolidated into one file prior to being assigned a randomly-selected order number. Because we are able to take corrective action prior to the assignment of randomly-selected order numbers, we have elected not to impose a penalty on individuals who file multiple petitions.

Another commenter urged us to publish petition forms in Spanish to accommodate those individuals who live in Spanish-speaking countries or territories (*e.g.*, Puerto Rico).

The Ricky Ray Program already has in place a Spanish version of the Ricky Ray Hemophilia Relief Fund Petition Form. It is available to petitioners upon request, and at the Ricky Ray website. In addition, we have also provided technical support in Spanish via the Ricky Ray toll-free Helpline.

Another commenter suggested that we use other media in addition to the **Federal Register** to publicize availability of the Ricky Ray Hemophilia Relief Fund.

The Ricky Ray Program Office (RRPO) has made a broad effort to publicize the Ricky Ray Hemophilia Relief Fund by contacting advocacy groups for persons with blood-clotting disorders, hemophilia treatment centers, and numerous health care providers to publicize the availability of the Program. In addition, the Department has issued press releases to the general media, and interviews have been conducted by various print and broadcast media groups. The RRPO implemented a website (*http://www.hrsa.gov/bhpr/rickyray*), installed a toll-free telephone number (1–888–496–0338), and made mass mailings to inform interested individuals of this Program.

Other commenters suggested that the Department expand the list of eligible survivors to include care providers and unmarried partners. In addition, one commenter stated that surviving parents of an eligible individual should be eligible to petition in conjunction with other survivors and receive a portion of the compassionate payment. This commenter also suggested that if the surviving spouse of an eligible individual remarries, his/her rights to apply as the eligible survivor should be forfeited, and the rights should pass to the next eligible survivor.

The interim final rule implements the provision of the Act that provides for payments to be made to specified survivors in a specific order. Section 103(c) of the Act provides for the payment to be made as follows: (1) To a surviving spouse who is living at the time of payment; (2) if there is no surviving spouse, the payment is to be made in equal shares to all children of the individual who are living at the time of payment; and (3) if there are no surviving spouse or surviving children, the payment is to be made in equal shares to the surviving parents of the eligible individual. If the individual is not survived by a person described in 1, 2, or 3 above, the payment will revert back to the Ricky Ray Hemophilia Relief Fund. The remarriage of an eligible spouse does not alter his/her statutory right to payment. In addition, the Act does not allow different classes of survivors to share in the payment. Only Congress can change the provisions of the Act.

One commenter suggested that the time frame for eligibility be expanded to include individuals who were treated with antihemophilic factor prior to July 1, 1982.

The time frame for qualifying for a compassionate payment from the Fund is established in section 102(a) of the Act. This section directs the Secretary to make a compassionate payment from the Fund to any individual with an HIV infection who has a blood-clotting disorder, such as hemophilia, and was treated with antihemophilic factor at any time between July 1, 1982, and December 31, 1987. Only Congress can change the provisions of the Act.

The Department received comments requesting that the Program allow individuals to petition on behalf of the estate of deceased individuals who had a blood-clotting disorder, received antihemophilic factor and contracted HIV. The commenters argued that in the event that a deceased individual has no survivors, the executor should be eligible to apply on behalf of the deceased individual and apply the payment to the estate.

The Act does not provide for the payment of claims to estates of deceased individuals who contracted HIV. That conclusion reflects a legislative decision made by Congress, as the statute leaves no room for a contrary result. In the case of the deceased individual with HIV, section 103(c) of the Act directs the Secretary to make payment first to a surviving spouse, then to all surviving children, and lastly to the surviving parents of the deceased individual. If there are no survivors within those categories, the Act requires that the payment revert back to the Fund.

The Department received a comment urging the Program to eliminate § 130.23(a)(2) of the interim final rule, which relates to the filing of an amendment by the next eligible survivor in the event that a petitioner dies before payment. The commenter suggested that this scenario could be addressed through the court system.

The Department does not concur with this comment. We believe it is essential to have mechanisms in place to allow all potentially eligible survivors to petition for payment. The effect of § 130.23(a)(2) is to allow eligible survivors to retain the assigned order number of an individual who filed a petition, but then died prior to receiving payment.

A commenter suggested that the RRPO allow the private sector to implement and administer the Ricky Ray Hemophilia Relief Fund Act. Further, the commenter urged us to bestow upon the private sector the duty of disbursing government funds.

In accordance with the Act, the Secretary of Health and Human Services is required to establish procedures under which individuals may submit petitions for payment under the Ricky Ray Hemophilia Relief Fund. Section 101(c) of the Act also provides that amounts in the Fund shall be available only for disbursement by the Secretary of Health and Human Services. We have contracted with private expert consultants, as needed, for the purpose of obtaining assistance in reviewing petitioners' eligibility for compassionate

payments, but we retain the functions of determining eligibility and making payments. This is a Federal Government Program, and payments must be disbursed through the Secretary of the Department.

The Department received a comment regarding the process by which the Secretary will determine whether a petition is complete. Specifically, § 130.33(d) of the interim final rule indicates that, following the issuance of an incomplete notice, the Secretary will continue to process a petition if the petitioner fails to complete the petition within the specified deadline or fails to make an adequate showing of good cause as to why the required documentation is unavailable. The commenter noted that, in the event that the petitioner fails to complete the petition, the intended language might have been for the Secretary not to finish processing the petition.

It is the intention of the Secretary to process fully all submitted petitions. In the event that a petition does not include all required documentation, and the petitioner fails to make an adequate showing of good cause as to why the required documentation is unavailable, despite the extension of time that may be given under the amendments to § 130.33(c) and (d)(2) herein, the petition will be processed and may be disapproved.

One commenter suggested that petitions receive a chance for full review, even if the appropriated funds are exhausted for FY 2000 and 2001. In addition, the commenter asked that a statement be released indicating that all petitions will be reviewed regardless of the availability of appropriated funds.

The Secretary will review fully each petition postmarked between July 31, 2000, and November 13, 2001, regardless of the status of the funding.

B. Documentation Required To Prove Eligibility

One commenter requested that the regulations be changed to allow physician assistants to submit the Confidential Physician and Nurse Practitioner Affidavit. The commenter noted that physician assistants are regulated and certified in all States and, in many instances, serve as the primary health care providers for potential petitioners.

The Department agrees with this comment. Therefore, we are amending § 130.20(b) of the regulations to allow physician assistants, as well as physicians and nurse practitioners, to submit affidavits verifying medical eligibility.

One commenter raised concerns about the use of documents from the Factor Concentrate Settlement as delineated in § 130.31(h) of the interim final rule. The commenter raised concerns about obtaining such documentation and notification regarding whether the documentation was sufficient for a petition under the Act.

As described in § 130.31(h) of the interim final rule, the RRPO will accept originals, or duplicate copies, of medical and legal documentation used in the Factor Concentrate Settlement (*Susan Walker* v. *Bayer Corporation, et al.*, 96–C–5024 (N.D. Ill)). However, it is the responsibility of the petitioner to obtain such documentation or to request, in writing, that it be released by the Settlement Administrator directly to the Ricky Ray Program. If the Ricky Ray petitioner is the same person who originally submitted documents in the settlement, the Settlement Administrator may provide copies of those documents to the petitioner. However, in cases where the petitioner is someone other than the person who submitted the documents in the Settlement, the U.S. District Court has approved procedures to expedite the Ricky Ray payment process and ensure that confidentiality is protected (Settlement Implementation Order No. 16, December 14, 2000).

This Order authorizes the Settlement Administrator to provide the documents needed to complete a Ricky Ray petition, if available, directly from the Settlement files to the Ricky Ray Program when a petitioner so requests by sending the Settlement Administrator a copy of the letter from the Program indicating what required documentation is missing from the petition. Requests, which must be in writing and include the copy of this letter, should be sent to: Factor Concentrate Settlement Litigation, Claims Administrator, 1777 Sentry Parkway West, Dublin Hall, Suite 400, Blue Bell, PA 19422.

It should be noted that whatever eligibility or payment decisions were made under the Factor Settlement, those decisions have no bearing whatsoever on such determinations under the Ricky Ray Program. Allowing petitioners to use their documents from the Factor Settlement files to complete their Ricky Ray petitions, when applicable, is merely a mechanism to aid petitioners in completing their petitions in the least burdensome and most expeditious manner.

C. The Payment Process

A commenter suggested that the RRPO collect the taxpayer identification number (TIN) of attorneys for the purpose of filing tax returns. The commenter stated that the Internal Revenue Service requires governmental units to collect TINs from attorneys when making payments which are income to attorneys, and to report those transactions via Form 1099–Misc informational returns.

In compliance with the statute, payments are made to petitioners and not to attorneys. Should the petitioner owe a portion of his or her payment to an attorney, within the limit of section 107 of the Act, the RRPO is not a party to that transaction and will not have information to report to the Internal Revenue Service.

The Department received a comment concerning the likelihood that the FY 2000 appropriation would be insufficient to pay all eligible petitioners. The commenter urged us to provide to each petitioner who files an approved petition and does not receive payment, a notice stating when the funds will be paid.

As stated earlier, since Congress now has appropriated $580 million to the Ricky Ray Hemophilia Relief Fund for FY 2001, we believe that there will be sufficient funds to pay all approved petitions.

The Department received several comments suggesting that we prioritize the payment process. The commenters advocated that individuals with a blood-clotting disorder and HIV should receive compassionate payments before survivors of deceased individuals.

Section 103(c)(1) of the Act requires us to make payments to individuals who file complete and approved petitions ''in the order received.'' The process described in the interim final rule was designed to comply with this provision of the statute. The Act does not provide for prioritizing payments to individuals who are living with a blood-clotting disorder and HIV over payments to eligible survivors.

One commenter expressed concern regarding the amount of payments. The interim final rule and section 102(a) of the Act both provide that ''* * * if there are sufficient amounts in the Fund to make each payment, the Secretary shall make a single payment of $100,000* * *'' to an eligible individual with HIV. The commenter questioned whether this provision could provide the basis for making partial payments if the Secretary determines that there are not sufficient funds available to make single payments of $100,000.

The Secretary has interpreted this provision as requiring full payments of $100,000 on behalf of each eligible

individual with HIV, to the extent that funds are available to make each individual payment.

D. The Reconsideration Process

The Department received comments regarding the reconsideration process for petitions denied payment. One commenter expressed concern that the reconsideration review panel be independent of, and not subject to influence from, the RRPO. In addition, another commenter asked where the request for reconsideration would have to be sent if different from the RRPO. The commenters also requested that the review process be clearly defined.

Every petitioner who files a petition and is denied payment may ask for reconsideration. As stated in § 130.40(a) of the interim final rule, the request must be sent to the Deputy Associate Administrator for Health Professions, Health Resources and Services Administration, Room 8A–54, 5600 Fishers Lane, Rockville, MD 20857. The request must be received within 60 calendar days of the date the petition was denied. The request should state the reasons that the petitioner is seeking reconsideration, but may not include any additional documentation not previously provided. The Deputy Associate Administrator will convene a panel to review all requests for reconsideration. The panel will consist of three individuals qualified to evaluate the petitions who are independent of the RRPO. The panel will review each case and make recommendations to the Deputy Associate Administrator. The recommendations of the review panel will be made independently of the RRPO. The Deputy Associate Administrator will review the recommendations and make the final determination.

Explanation of Provisions

Section 130.20(b) of the interim final rule currently provides that the medical documentation required to prove that an individual is eligible for payment may be submitted in the form of relevant medical records or of an affidavit, signed under penalty of perjury, by a physician or nurse practitioner, verifying that the individual had a blood-clotting disorder, such as hemophilia, received antihemophilic factor between July 1, 1982, and December 31, 1987, and was diagnosed as having HIV.

As previously noted, we are herein amending § 130.20(b) of the interim final rule to allow physician assistants, as well as physicians or nurse practitioners, to submit such sworn affidavits to verify medical eligibility. Although we are not amending the sample affidavit in Appendix B to the final rule to reflect this addition, we will accept the affidavit when completed and signed by a physician assistant. This will apply to affidavits from physician assistants for petitions that have not yet been reviewed. According to the comment received on this issue, licensure terminology *per se* is not used by all States for physician assistants. Therefore, in the space currently provided in Section C of the affidavit for ''License Number and State Where Licensed'' physician assistants must include their State certification or registration number (and name of State) if a license number is not applicable.

A new § 130.24 is added to Subpart C stating that, where a petition raises an eligibility or payment question, the Secretary may require additional documentation to resolve the issue. For example, where the medical records submitted are inconclusive in establishing HIV infection, a sworn affidavit verifying satisfaction of the medical criteria necessary for eligibility, or evidence of one or more of the opportunistic diseases listed in Appendix A may be required.

Under the Act and regulations, if the person with HIV is no longer living and is not survived by a spouse or children who are living at the time of payment, the compassionate payment is made in equal shares to the surviving parents (§ 130.11(b)(3)). If one parent is deceased, the sole surviving parent is eligible to receive the full payment of $100,000. In order for the Secretary to determine the appropriate amount of the payment to be made, a petitioner filing a petition designating him/herself to be the sole surviving parent must provide proof of death, or termination of parental rights, of the other parent. Where a parent is seeking the full $100,000 payment but cannot document that the other parent is deceased, proof of termination of parental rights or other evidence establishing eligibility for the full payment would be required to determine the proper payment amount.

The RRPO may make compassionate payments for the benefit of a legally incompetent individual (i.e., a minor or other individual who does not have the legal capacity to receive payment directly). However, in order to ensure that these payments are, in fact, used for their benefit, we are requiring that evidence of a guardianship (sometimes called a conservatorship) established in accordance with applicable State and local laws, as well as proof of a guardianship account, be provided before a compassionate payment can be made for the benefit of these individuals. Payments will be made electronically to the guardianship account. If these requirements have not been met at the time the petition is submitted, the RRPO will not delay review of the petition.

Although there may be a time and cost burden associated with the establishment of a guardianship and guardianship account (all fees associated with these requirements are to be borne by the petitioner), persons without legal capacity to receive payments who participated in the Factor Concentrate Settlement (*i.e.,* the *Walker* v. *Bayer* case) may already have established such an account. If so, this would reduce any burden associated with the requirements of this policy, since it is unnecessary to establish a separate guardianship account specifically for payments made under the Ricky Ray Program.

We recognize that the personal representative (such as a parent, guardian, or attorney) who files the petition on behalf of a minor or other legally incompetent individual may not be the guardian of that person's property and, therefore, would not have the authority to receive the payment on his/her behalf. It is the responsibility of the personal representative filing the petition to submit the documentation showing that the guardianship and guardianship account have been set up as required, before payment can be made.

Further information regarding the RRPO policy on payments for the benefit of minors and legally incompetent adults is available on the Ricky Ray website at *http://www.hrsa.gov/bhpr/rickyray*.

Currently, § 130.33 provides that, as a part of the petition review process, if we determine that a petition is incomplete, we so notify the petitioner and give the petitioner 60 days from the date of notification to submit the missing information. In the event that the petitioner is unable to secure the required documentation to complete the petition, the petitioner may submit written documentation to the Secretary within the 60 days showing good cause as to why the required legal and/or medical evidence is not available.

In the interest of minimizing the burden on those who may be eligible for payment but who are having difficulty obtaining the required medical or legal documentation, the Department has determined that it may be helpful for some petitioners to have additional time beyond the 60-day deadline, at the discretion of the Secretary, in which to provide missing documentation and,

thereby, complete their petitions. Thus, we are amending § 130.33(c) to allow for this additional time, as the Secretary may deem appropriate, for petitioners to obtain and submit their missing documentation before the Secretary makes a final determination of eligibility. We are amending § 130.33(d)(2) as well and believe that we are thereby giving petitioners every opportunity to submit evidence of their eligibility where additional time would enable them to do so.

Technical Amendments

Technical amendments are being made to part 130 to add at the end of §§ 130.20, 130.21, 130.22, 130.23, 130.24, 130.30, and 130.31 a parenthetical statement indicating that these sections contain information collection requirements that have been reviewed and given an approval number by the Office of Management and Budget.

Justification of Waiver of Delay of Effective Date

The Secretary has found that a delay in the effective date of these amendments is unnecessary and contrary to the public interest. The amendments enable the RRPO to facilitate making compassionate payments to eligible petitioners with no additional burdens. They have no effect on any individual's rights or responsibilities.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act (RFA) of 1980, if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Department has determined that resources to implement this final rule are required only of petitioners in submitting their petitions and of the Department in reviewing them. Therefore, in accordance with the RFA of 1980, and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities. The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures.

We have determined that the final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. We have made this decision because Congress, not the Department, determined the amount of the compassionate payment to be disbursed to eligible petitioners under the Act. In promulgating this final rule, the Department is not exercising any discretion as to the amount of money given to petitioners deemed eligible under the Act.

Impact on Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed or final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will impose no direct requirement costs on State and local governments, does not preempt State law, or have any Federalism implications.

Impact on Family Well-Being

The Secretary has determined that, by implementing the provision of compassionate payments to eligible petitioners, this final rule has a positive effect on family well-being. Therefore, in accordance with Section 654(c) of the Treasury and General Government Appropriations Act of 1999, the Department has assessed the impact of the rule on the seven elements of family well-being specified in the law, namely: family safety, family stability; marital commitment; parental rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; and the behavior and personal responsibility of youth. The only element on which this rule has an impact is disposable income or poverty. The rule has a positive impact on disposable income or poverty because it implements the provision of compassionate payments of $100,000 to eligible petitioners without imposing a corresponding burden on them.

Paperwork Reduction Act

The information collection requirements set forth in the final rule under §§ 130.20, 130.21, 130.22, 130.23, 130.24, 130.30, and 130.31 for the Ricky Ray Hemophilia Relief Fund (45 CFR part 130) have been approved under OMB No. 0915–0244. This approval included an extensive 60-day agency review and public comment period on the information collections requirements set forth in rulemaking.

List of Subjects in 42 CFR Part 130

Blood diseases, HIV/AIDS, Indemnity payments, Reporting and recordkeeping requirements.

Dated: June 29, 2001.

Elizabeth M. Duke,

Acting Administrator, Health Resources and Services Administration.

Approved: August 30, 2001.

Tommy G. Thompson,

Secretary.

For the reasons stated above, the Department of Health and Human Services is adopting the interim final rule adding 42 CFR chapter I, subchapter L and part 130, published at 65 FR 34860 on Wednesday, May 31, 2000, as a final rule with the following changes:

SUBCHAPTER L—COMPASSIONATE PAYMENTS

PART 130—RICKY RAY HEMOPHILIA RELIEF FUND PROGRAM

1. The authority citation for part 130 continues to read as follows:

Authority: Secs. 101–108 of Pub. L. 105–369, 112 Stat. 3368 (42 U.S.C. 300c–22 note); sec. 215 of the Public Health Service Act (42 U.S.C. 216).

Subpart C—Documentation Required for Complete Petitions

2. Section 130.20 is amended by revising the first and second sentence in paragraph (b); and by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.20 Form of medical documentation.

* * * * *

(b) An affidavit, signed under penalty of perjury, by a physician, nurse practitioner or physician assistant, verifying that the medical criteria necessary for a petitioner to be eligible for payment under the Act are satisfied. Such an affidavit must include the physician's, nurse practitioner's or

physician assistant's State of practice, and license, certification or registration number, as applicable. * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

3. Section 130.21 is amended by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.21 What documentation is required for petitions filed by living persons with HIV?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

4. Section 130.22 is amended by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.22 What documentation is required for petitions filed by survivors of persons with HIV, which are filed in cases where the person with HIV dies before filing a petition?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

5. Section 130.23 is amended by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.23 What documentation is required for amendments to petitions, which are filed by survivors of persons with HIV?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

6. A new § 130.24 is added to subpart C to read as follows:

§ 130.24 What additional documentation may the Secretary require to resolve eligibility or payment issues?

(a) In addition to the applicable documentation required under this subpart, the Secretary may require the petitioner to provide other documentation, as the Secretary deems appropriate, to resolve issues of eligibility, or of the procedure for payment, raised by a petition.

(b) Where a petition filed on behalf of a minor or other individual who is legally incompetent to receive payment has been approved for payment, the personal representative filing the petition on the individual's behalf must submit the following before payment can be made for the legally incompetent individual:

(1) Documentation of a guardianship or conservatorship, established in accordance with State and local law; and

(2) Information identifying a guardianship or conservatorship account.

(Approved by the Office of Management and Budget under control number 0915–0244.)

Subpart D—Procedures for Filing and Paying Complete Petitions

8. Section 130.30 is amended by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.30 Who may file a petition for payment or an amendment to a petition?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

9. Section § 130.31 is amended by adding a parenthetical phrase at the end of the section to read as follows:

§ 130.31 How and when is a petition for payment filed?

* * * * *

(Approved by the Office of Management and Budget under control number 0915–0244.)

10. Section 130.33 is amended by adding a sentence at the end of paragraph (c), and by revising paragraph (d)(2) to read as follows:

§ 130.33 How will the Secretary determine whether a petition is complete?

* * * * *

(c) * * * The Secretary may allow additional time beyond the 60-day deadline, as the Secretary deems appropriate, for the petitioner to provide the documentation required to complete the petition.

(d) * * *

(2) The 60-day deadline, or the extended deadline under § 130.33(c), as applicable, to complete the petition is not met; or

* * * * *

[FR Doc. 01–29173 Filed 11–21–01; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 1355, 1356 and 1357

Administration for Children and Families

Title IV–E Foster Care Eligibility Reviews and Child and Family Services State Plan Reviews; Technical Corrections

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services (DHHS).

ACTION: Technical corrections.

SUMMARY: The Administration for Children and Families is correcting the final rule on Title IV–E Foster Care Eligibility Reviews and Child and Family Services State Plan Reviews published on January 25, 2000 (65 FR 4019–4093), and related regulations at 45 CFR parts 1355, 1356 and 1357.

DATES: Effective November 23, 2001. Comments accepted until January 22, 2002.

ADDRESSES: Please address comments to Kathleen McHugh, Director of Policy, Children's Bureau, Administration on Children, Youth and Families, 330 C Street, SW., Washington, DC 20447. Comments will not be accepted by telephone.

FOR FURTHER INFORMATION CONTACT: Kathleen McHugh, Children's Bureau, 202–401–5789.

SUPPLEMENTARY INFORMATION:

I. Background

The Administration on Children, Youth and Families published a final rule on the title IV–E foster care eligibility reviews and the child and family services reviews on January 25, 2000, in the **Federal Register** (65 FR 4019–4093). The purpose of the final rule was to implement reviews of title IV–E foster care maintenance payments and title IV–B and IV–E State plan requirements. The final rule also implemented certain requirements of the Social Security Act Amendments of 1994; the Multiethnic Placement Act of 1994, as amended; and the Adoption and Safe Families Act of 1997. The effective date of the rule was March 27, 2000.

II. Need for Technical and Correcting Amendments in 45 CFR Parts 1355, 1356 and 1357

In reviewing the final rule, we have identified several technical errors, omissions, and obsolete references in the final regulations. In addition, certain sections of the existing regulations conflict with recent changes in Federal child welfare legislation. We are making these technical, conforming amendments to correct and clarify the regulations.

Waiver of Notice and Comment Procedures

The Administrative Procedure Act (5 U.S.C. 55(b)(B)) requires that the Department publish a Notice of Proposed Rulemaking unless the Department finds, for good cause, that such notice is impracticable, unnecessary, or contrary to the public interest. In this instance, we are making only technical, nonsubstantive clarifications, corrections, and conforming amendments. Accordingly,

the Department has determined that it would be unnecessary to use notice and comment procedures. We will, however, consider comments received within 60 days of publication in the **Federal Register**.

Regulatory Text

We have made the following technical corrections in the regulatory text:

Corrections to Part 1355

• We have removed the definition of Independent Living Program (ILP) in § 1355.20(a). The Foster Care Independence Act of 1999 (12/14/99), Public Law 106–169, renamed and significantly revised the program at section 477 of the Social Security Act (the Act), which makes the regulatory definition obsolete.

• In § 1355.20(a), we amended the definition of Child abuse and neglect to remove the prior cross-reference to an obsolete definition in 45 CFR 1340.2. The Child Abuse Prevention and Treatment Act (CAPTA) Amendments of 1996 changed the definition of child abuse and neglect. Therefore, we have cross-referenced the statutory citation rather than the regulatory definition.

• We made the definition of State in § 1355.20(a) consistent with Title IV–A of the Act (section 402(a)(3) and section 419(5)). Title IV–A requires a State that operates a Temporary Assistance for Needy Families (TANF) program to certify that it will also operate a program under an approved title IV–E State plan. Title IV–A defines ''State'' as the 50 States, District of Columbia, Puerto Rico, the United States Virgin Islands, Guam and American Samoa (section 419(5) of the Act). We are adding Puerto Rico, the Virgin Islands, Guam and American Samoa to the definition in § 1355.20 for consistency.

• In the definition of Statewide assessment in § 1355.20(a) we added a cross-reference to the specific sections in 1355.33 that contain the requirements for a statewide assessment.

• We corrected the placement of § 1355.20(b) so that it follows the entire § 1355.20(a). As published, paragraph (b) was misplaced so that it appeared prior to the definition of Statewide assessment in § 1355.20(a).

• We amended § 1355.30(n)(2) to correct the prior cross-reference to 45 CFR 201.6. In accordance with section 1123A of the Act, we established procedures in the final rule for determinations regarding lack of compliance with title IV–B and IV–E State plan provisions; accordingly, the procedures prescribed by § 201.6 are applicable only with respect to lack of compliance arising out of an unapprovable change in an approved State plan or the failure of a State to change its approved plan to conform to a new Federal requirement for approval of State plans.

• We deleted § 1355.30(n)(3), which cross-references 45 CFR 201.7, since there is no statutory basis for a direct appeal to a Federal Appeals Court from a Departmental Appeals Board decision pertaining to Social Security Act titles IV–B or IV–E. *California Department of Social Services v. Shalala*, 166F.3d 1019 (9th Circuit 1999).

• In § 1355.32(d)(4), we added the words, ''if the provisions for such a plan are applicable'' to the first sentence to eliminate an inconsistency between the statute and the regulation. The statute does not allow for program improvement prior to a penalty for every instance of noncompliance with a State plan requirement in titles IV–B or IV–E of the Act. Specifically, section 474(d)(1) of the Act makes specific provisions for penalties and corrective action for violations of section 471(a)(23) of the Act.

• We have amended § 1355.33(b)(2) to allow States to use an alternative data source for the National Child Abuse and Neglect Data System (NCANDS) in any child and family services review. As originally published the regulatory language limited the use of alternative child safety data to the initial child and family services review. However, NCANDS is a voluntary reporting system and we did not intend to require States to report data to NCANDS, although it is our preferred data source.

• In § 1355.33(b), we corrected the numbering for the last two paragraphs of that section, which were incorrectly numbered as paragraphs (b)(1) and (b)(2). They are now numbered as paragraphs (b)(5) and (b)(6).

• In § 1355.33(c)(6) we clarified that the oversample for the child and family services reviews will consist of up to 150 foster care cases and 150 in-home services cases. To make sure that there is an adequate oversample from which to pull additional cases when needed, we must ensure that there are a sufficient number of cases of each type. In this paragraph, we also clarified the language with regard to the discrepancy resolution process. As stated in § 1355.33(d), we will use the process to resolve discrepancies between information in the statewide assessment and the on-site review. The prior language in § 1355.33(c)(6), however, restricted use of the resolution process to discrepancies between statewide data indicators and the on-site review. As the amended regulation makes clear, we allow a State to submit additional information or review additional cases when a discrepancy exists between the statewide assessment and the on-site review.

• We corrected § 1355.33(d)(2), to specify that the oversample for the child and family services reviews will consist of no more than 150 foster care cases and 150 in-home services cases.

• The prior regulatory language in § 1355.34(b)(4) required the Secretary to develop statewide data indicators for every outcome, but it is not currently possible to do this for well-being outcomes, since well-being measures are not typically captured in State information systems or reported to AFCARS. Therefore, we have amended the section to allow but not require the Secretary to develop statewide data indicators for outcomes where they do not currently exist.

• In § 1355.34(c)(2)(v), we removed an inconsistency between two sections of the regulation. We have clarified that, in a child and family services review, we will review the State plan requirement that notice and opportunity to be heard is provided to foster parents, preadoptive parents and relative caretakers in permanency hearings and six-month periodic reviews. The prior language stated that we would review to the standard that notice and opportunity be provided in any review or hearing held with respect to the child. The new language conforms to the State plan requirement as implemented by § 1356.21(o).

• We corrected § 1355.34(c)(4)(v), to make it consistent with the regulatory requirements in § 1357.15 regarding training.

• We made an editorial change in § 1355.35(e)(1), to remove the word ''subsequent.''

• In § 1355.36(b)(5)(i), we corrected the terminology to clarify that withholding applies when one of the seven outcomes listed in § 1355.34(b)(1) is determined to be out of ''substantial conformity.'' The prior reference to ''substantially achieved '' was inaccurate because that term applies only to the review of cases on-site.

• We corrected the penalty references in § 1355.38. The published rule followed the statutory requirement that an entity must remit title IV–E funds to the Secretary when it is determined to have violated section 471(a)(18) of the Act, but did not specify a procedure. In § 1355.38(b)(1), we added cross-references to paragraphs that specify when and how the entity will be penalized for violating section 471(a)(18) of the Act. Entities that violate section 471(a)(18) of the Act with regard to a person, as determined

by a DHHS investigation, will be penalized according to paragraph (g)(2) of this section. Entities that violate section 471(a)(18) of the Act, as determined by a court finding will be penalized according to paragraph (g)(4) of this section.

• In § 1355.38(b)(4), we clarify that entities, like States, must notify ACF within 30 days of a final court finding of a violation of section 471(a)(18) of the Act.

• We corrected § 1355.38(f) to reflect the new name of the former Independent Living Program. Public Law 106–169 changed the name of the Independent Living Program to the ''Chafee Foster Care Independence Program.''

• We included the term ''entity'' in the last sentence of § 1355.38(g)(1)(i) in order to highlight paragraph (h) of this section as the relevant paragraph for details on how entities must remit funds for violating section 471(a)(18) of the Act.

• In § 1355.38(g)(2), we clarify that an entity must remit the funds paid to it by the State during the quarter in which it is notified by ACF of a section 471(a)(18) violation.

• We corrected § 1355.38(g)(4) to specify that entities must also remit title IV–E funds to the Secretary, when a court finds that the entity has violated section 471(a)(18) of the Act, for the quarter during which the court makes the finding.

• In § 1355.38(h), we added a reference to section 474(d)(2) of the Act to incorporate the statutory enforcement authority.

• We added cross references to paragraphs (g)(2) and (g)(4) in § 1355.38(h)(2) to clarify the distinction between the penalty provisions for entities that are found to have violated section 471(a)(18) of the Act with regard to an individual as a result of an DHHS investigation and as a result of a court finding. The prior language inaccurately required entities to remit funds for the quarter in which they are notified of a violation in both circumstances. In fact, however, when an entity is found to have violated section 471(a)(18) of the Act as a result of a court finding, it is to remit funds for the quarter in which the court finding was made.

• We amended the parenthetical note following § 1355.40 to remove an obsolete date and insert language consistent with the requirements of the Paperwork Reduction Act of 1995.

Corrections to Part 1356

• We deleted § 1356.20(c), as it has been superseded by the 1994 amendments to the Social Security Act made by Public Law 104–432. Section 1356.20 applied the withholding of payment provisions in 45 CFR 201.6(e) to AFCARS. However, section 1123A of the Act applies to AFCARS.

• We corrected the parenthetical note following § 1356.20 to include language that is consistent with the Paperwork Reduction Act of 1995, Public Law 104–13.

• We corrected the cross-reference in § 1356.21(b)(1)(i) to accurately reference physical or constructive removals, but not voluntary placements, as the starting point for determining when a judicial determination of reasonable efforts to prevent a child's removal from the home is necessary for title IV–E purposes. The prior cross-reference might have been misinterpreted as requiring judicial determinations of reasonable efforts to prevent a child's removal from the home in voluntary placement situations.

• We corrected § 1356.21(b)(2)(ii) to clarify that a State may not claim Federal Financial Participation (FFP) for an otherwise eligible child from the date when it should have obtained a judicial determination with regard to reasonable efforts to finalize a permanency plan until the State actually obtains such a determination.

• We correct the parenthetical note following § 1356.21(g)(5) to insert language consistent with current Paperwork Reduction Act requirements.

• In § 1356.21(i)(1)(i)(A), we added a cross-reference for the regulatory definition of the date a child is considered to have entered foster care.

• In § 1356.21(j), we added the citation for the definition of foster care maintenance payments.

• Prior § 1356.21(k)(1)(i) implied that a relative has the authority to enter into a voluntary placement agreement that leads to a child's removal from the home for title IV–E purposes. The statute at section 472(f) of the Act, however, limits this authority to parents and guardians. Accordingly, we have corrected the language in this section to conform with the statute.

• In § 1356.22(a)(3), we are adding a cross-reference to § 1356.21(e) pertaining to trial home visits to the voluntary placement agreement requirements.

• In § 1356.50, we have corrected the cross-references in paragraph (c) so that the new appeal procedures outlined in § 1355.39 apply.

• We deleted the parenthetical note following § 1356.60 because the OMB control number cited was no longer valid. The information collection referred to was the quarterly financial report for a State's expenditures and estimates of title IV–E funds. That reporting form (ACF–IV–E–1) displays the current OMB control number; thus, it is unnecessary to publish the number in regulation.

• We reorganized § 1356.71(a)(3) for clarity and clarified the timeframe for subsequent title IV–E foster care eligibility reviews in new § 1356.71(a)(3)(ii). While it was intended that all States have a subsequent review at three-year intervals as stated in the preamble discussion on page 4072 of the published rule, we did not expressly address the situation of States that are found to be out of substantial compliance in the primary review. Such States, in accordance with the general rule, must have another primary review within three years of the previous secondary review.

• We have clarified § 1356.71(j)(2) so that, as explained in the preamble at page 4073 of the published rule, administrative costs claimed under title IV–E associated with ineligible cases, will be disallowed.

• We have deleted § 1356.80, which was rendered obsolete by the enactment of Public Law 106–169.

Corrections to Part 1357

• We deleted the prior note following § 1357.15 because it was obsolete. We have provided the current OMB control number for the child and family services plan and language consistent with the Paperwork Reduction Act.

• We made the same changes regarding the OMB control number for the note following § 1357.16 with regard to the annual progress and services report.

Impact Analysis

No impact analysis is needed for these technical corrections. The impact of the necessary corrections falls within the analysis of the final rule published in the **Federal Register** on January 25, 2000 (65 FR 4019–4093).

List of Subjects

45 CFR Part 1355

Adoption and foster care, child welfare, Grant programs—Social programs.

45 CFR Part 1356

Adoption and foster care, Grant programs—Social programs.

45 CFR Part 1357

Child and family services, child welfare, Grant programs-Social programs.

(Catalog of Federal Domestic Assistance Program Numbers 93.658, Foster Care

Maintenance; 93.659, Adoption Assistance; and 93.645, Child Welfare Services—State Grants)

Dated: October 16, 2001.

Brian P. Burns,

Deputy Assistant Secretary for Information Resources and Management.

For the reasons set forth in the preamble, 45 CFR parts 1355, 1356, and 1357 are amended by making the following technical changes, corrections and amendments:

PART 1355—GENERAL

1. The authority citation for part 1355 continues to read as follows:

Authority: 42 U.S.C. 620 *et seq.*, 42 U.S.C. 670 *et seq.*, 42 U.S.C. 1302.

2. Amend § 1355.20(a) by:

a. Removing the definition of *Independent Living Program (ILP);*

b. Revising the definition of *Child abuse and neglect;*

c. Revising the second sentence of the definition of *State;*

d. Revising the definition of *Statewide assessment;* and

e. Correctly designating paragraph (b) to follow the definition of *Statewide assessment.*

The revisions read as follows:

§ 1355.20 Definitions.

(a) * * * * *

Child abuse and neglect means the definition contained in 42 U.S.C. 5106(g)(2).

* * * * *

State * * * For title IV–E the term ''State'' means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, and American Samoa.

* * * * *

Statewide assessment means the initial phase of a full review of all federally-assisted child and family services programs in the States, including family preservation and support services, child protective services, foster care, adoption, and independent living services as described in § 1355.33(b) of this part, for the purpose of determining the State's substantial conformity with the State plan requirements of titles IV–B and IV–E as listed in § 1355.34 of this part.

* * * * *

3. Amend § 1355.30 by revising paragraph (n)(2), removing paragraph (n)(3), and redesignating paragraphs (n)(4) and (n)(5) as paragraphs (n)(3) and (n)(4) respectively to read as follows:

§ 1355.30 Other applicable regulations.

* * * * *

(n) * * *

(2) § 201.6—Withholding of payment; reduction of Federal financial participation in the costs of social services and training. (Applicable only to an unapprovable change in an approved State plan, or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.)

* * * * *

4. Amend the first sentence in § 1355.32(d)(4) to read as follows:

§ 1355.32 Timetable for the reviews.

* * * * *

(d) * * *

(4) If the partial review determines that the State is not in compliance with the applicable State plan requirement, the State must enter into a program improvement plan designed to bring the State into compliance, if the provisions for such a plan are applicable. * * *

5. Amend § 1355.33 by:

a. Revising paragraph (b)(2);

b. Correctly designating the second occurrence of paragraphs (b)(1) and (2) as (b)(5) and (6);

c. Revising the first and third sentences of paragraph (c)(6); and

d. Revising the second sentence of paragraph (d)(2).

The revisions read as follows:

§ 1355.33 Procedures for the review.

* * * * *

(b) * * *

(2) Assess the outcome areas of safety, permanence, and well-being of children and families served by the State agency using data from AFCARS and NCANDS. For the initial review, ACF may approve another data source to substitute for AFCARS, and in all reviews, ACF may approve another data source to substitute for NCANDS. The State must also analyze and explain its performance in meeting the national standards for the statewide data indicators;

* * * * *

(c) * * *

(6) The sample of 30–50 cases reviewed on-site will be selected from a randomly drawn oversample of no more than 150 foster care and 150 in-home services cases. * * * The additional cases in the oversample not selected for the on-site review will form the sample of cases to be reviewed, if needed, in order to resolve discrepancies between the statewide assessment and the on-site reviews in accordance with paragraph (d)(2) of this section.

(d) * * *

(2) * * * ACF and the State will determine jointly the number of additional cases to be reviewed, not to exceed 150 foster care cases or 150 in-home services cases to be selected as specified in paragraph (c)(6) of this section.

* * * * *

6. Amend § 1355.34 by revising the first two sentences of paragraph (b)(4) and paragraphs (c)(2)(v) and (c)(4)(v) to read as follows:

§ 1355.34 Criteria for determining substantial conformity.

* * * * *

(b) * * *

(4) The Secretary may, using AFCARS and NCANDS, develop statewide data indicators for each of the specific outcomes described in paragraph (b)(1) of this section for use in determining substantial conformity. The Secretary may add, amend, or suspend any such statewide data indicator(s) when appropriate.

* * * * *

(c) * * *

(2) * * *

(v) Provide foster parents, preadoptive parents, and relative caregivers of children in foster care with notice of and an opportunity to be heard in permanency hearings and six-month periodic reviews held with respect to the child (sections 422(b)(10)(B)(ii), 475(5)(G) of the Act, and 45 CFR 1356.21(o)).

* * * * *

(4) * * *

(v) Provides training for current or prospective foster parents, adoptive parents, and the staff of State-licensed or State-approved child care institutions providing care to foster and adopted children receiving assistance under title IV–E that addresses the skills and knowledge base needed to carry out their duties with regard to caring for foster and adopted children.

* * * * *

7. Amend § 1355.35 by revising paragraph (e)(1) to read as follows:

§ 1355.35 Program improvement plans.

* * * * *

(e) * * *

(1) The methods and information used to measure progress must be sufficient to determine when and whether the State is operating in substantial conformity or has reached the negotiated standard with respect to statewide data indicators that failed to meet the national standard for that indicator;

* * * * *

8. Amend § 1355.36 by revising paragraph (b)(5)(i) to read as follows:

§ 1355.36 Withholding Federal funds due to failure to achieve substantial conformity or failure to successfully complete a program improvement plan.

* * * * *

(b) * * *

(5) * * *

(i) Except as provided for in paragraphs (b)(7) and (b)(8) of this section, an amount equivalent to one percent of the funds described in paragraph (b)(4) of this section for each of the years to which withholding applies will be withheld for each of the seven outcomes listed in § 1355.34(b)(1) of this part that is determined not to be in substantial conformity; and

* * * * *

9. Amend § 1355.38 by revising the first two sentences of paragraph (b)(1) and paragraphs (b)(4), (f), (g)(1)(i), (g)(4), (h) introductory text, and (h)(2) to read as follows:

§ 1355.38 Enforcement of section 471(a)(18) of the Act regarding the removal of barriers to interethnic adoption.

* * * * *

(b)(1) A State or entity found to be in violation of section 471(a)(18) of the Act with respect to a person, as described in paragraphs (a)(2)(i) and (a)(2)(ii) of this section, will be penalized in accordance with paragraph (g)(2) of this section. A State or entity determined to be in violation of section 471(a)(18) of the Act as a result of a court finding will be penalized in accordance with paragraph (g)(4) of this section.* * *

* * * * *

(4) A State or entity found to be in violation of section 471(a)(18) of the Act by a court must notify ACF within 30 days from the date of entry of the final judgement once all appeals have been exhausted, declined, or the appeal period has expired.

* * * * *

(f) *Funds to be withheld.* The term ''title IV–E funds'' refers to the amount of Federal funds advanced or paid to the State for allowable costs incurred by a State for: foster care maintenance payments, adoption assistance payments, administrative costs, and training costs under title IV–E and includes the State's allotment for the Chafee Foster Care Independence Program under section 477 of the Act.

(g) * * *

(1) * * *

(i) A determination that a State or entity is in violation of section 471(a)(18) of the Act with respect to a person as described in paragraphs (a)(2)(i) and (a)(2)(ii) of this section, or:

* * * * *

(2) Once ACF notifies a State (in writing) that it has committed a section 471(a)(18) violation with respect to a person, the State's title IV–E funds will be reduced for the fiscal quarter in which the State received written notification and for each succeeding quarter within that fiscal year or until the State completes a corrective action plan and comes into compliance, whichever is earlier. Once ACF notifies an entity (in writing) that it has committed a section 471(a)(18) violation with respect to a person, the entity must remit to the Secretary all title IV–E funds paid to it by the State during the quarter in which the entity is notified of the violation.

* * * * *

(4) If, as a result of a court finding, a State or entity is determined to be in violation of section 471(a)(18) of the Act, ACF will assess a penalty without further investigation. Once the State is notified (in writing) of the violation, its title IV–E funds will be reduced for the fiscal quarter in which the court finding was made and for each succeeding quarter within that fiscal year or until the State completes a corrective action plan and comes into compliance, whichever is sooner. Once an entity is notified (in writing) of the violation, the entity must remit to the Secretary all title IV–E funds paid to it by the State during the quarter in which the court finding was made.

* * * * *

(h) *Determination of the amount of reduction of Federal funds.* ACF will determine the reduction in title IV–E funds due to a section 471(a)(18) violation in accordance with section 474(d)(1) and (2) of the Act.

* * * * *

(2) Any entity (other than the State agency) which violates section 471(a)(18) of the Act during a fiscal quarter must remit to the Secretary all title IV–E funds paid to it by the State in accordance with the procedures in paragraphs (g)(2) or (g)(4) of this section.

* * * * *

§ 1355.40 [Amended]

10. Revise the parenthetical note following § 1355.40 to read as follows:

(This requirement has been approved by the Office of Management and Budget under OMB Control Number 0980–0267. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.)

PART 1356—REQUIREMENTS APPLICABLE TO TITLE IV–E

11. The authority citation for part 1356 continues to read as follows:

Authority: 42 U.S.C. 620 et seq., 42 U.S.C. 670 et seq., 42 U.S.C. 1302.

12. Amend § 1356.20 by removing paragraph (c), redesignating paragraphs (d) through (f) as paragraphs (c) through (e) respectively, and revising the parenthetical note following the section to read as follows:

§ 1356.20 State plan document and submission requirements.

* * * * *

(This requirement has been approved by the Office of Management and Budget under OMB Control Number 0980–0141. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.)

13. Amend § 1356.21 by:

a. Revising paragraphs (b)(1)(i) and (b)(2)(i);

b. Revising the parenthetical note following paragraph (g)(5);

c. Revising paragraph (i)(1)(i)(A);

d. Revising the second sentence of paragraph (j); and

e. Revising paragraph (k)(1)(i).

The revisions read as follows:

§ 1356.21 Foster care maintenance payments program implementation requirements.

* * * * *

(b) * * *

(1) * * *

(i) When a child is removed from his/her home, the judicial determination as to whether reasonable efforts were made, or were not required to prevent the removal, in accordance with paragraph (b)(3) of this section, must be made no later than 60 days from the date the child is removed from the home pursuant to paragraph (k)(1)(ii) of this section.

(2) * * *

(ii) If such a judicial determination regarding reasonable efforts to finalize a permanency plan is not made in accordance with the schedule prescribed in paragraph (b)(2)(i) of this section, the child becomes ineligible under title IV–E at the end of the month in which the judicial determination was required to have been made, and remains ineligible until such a determination is made.

* * * * *

(g) * * *

(5) * * *

(This requirement has been approved by the Office of Management and Budget under OMB Control Number 0980–0140. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.)

* * * * *

(i) * * *

(1) * * *

(i) * * *

(A) Must calculate the 15 out of the most recent 22 month period from the date the child is considered to have entered foster care as defined at section 475(5)(F) of the Act and § 1355.20 of this part;

(j) * * * Said costs must be limited to funds expended on items listed in the definition of *foster care maintenance payments* in § 1355.20 of this part.

(k) * * *

(1) * * *

(i) A voluntary placement agreement entered into by a parent or guardian which leads to a physical or constructive removal (i.e., a non-physical or paper removal of custody) of the child from the home; or

* * * * *

14. Amend § 1356.22 by revising paragraph (a)(3) to read as follows:

§ 1356.22 Implementation requirements for children voluntarily placed in foster care.

(a) * * *

(3) 45 CFR 1356.21(e), (f), (g), (h), and (i); and

* * * * *

15. Amend § 1356.50 by revising paragraph (c) to read as follows:

§ 1356.50 Withholding of funds for noncompliance with the approved title IV–E State plan.

* * * * *

(c) For purposes of this section, the procedures in § 1355.39 of this chapter apply.

16. Remove the parenthetical note following § 1356.60.

17. Amend § 1356.71 by revising paragraph (a)(3) and revising the third sentence of paragraph (j)(2) to read as follows:

§ 1356.71 Federal review of the eligibility of children in foster care and the eligibility of foster care providers in title IV–E programs.

(a) * * *

(3) The review process begins with a primary review of foster care cases for the title IV–E eligibility requirements.

(i) *States in substantial compliance.* States determined to be in substantial compliance based on the primary review will be subject to another review in three years.

(ii) *States not in substantial compliance.* States that are determined not to be in substantial compliance based on the primary review will develop and implement a program improvement plan designed to correct the areas of noncompliance. A secondary review will be conducted after the completion of the program improvement plan. A subsequent primary review will be held three years from the date of the secondary review.

* * * * *

(j) * * *

(2) * * * If both the case ineligibility and dollar error rates exceed 10 percent, the State is not in compliance and an additional disallowance will be determined based on extrapolation from the sample to the universe of claims paid for the duration of the AFCARS reporting period (*i.e.,* all title IV–E funds expended for a case during the quarter(s) that case is ineligible, including administrative costs). * * *

* * * * *

§ 1356.80 [Amended]

18. Remove § 1356.80.

PART 1357—REQUIREMENTS APPLICABLE TO TITLE IV–B

19. The authority citation for Part 1357 continues to read as follows:

Authority: 42 U.S.C. 620 *et seq.*, 42 U.S.C. 670 *et seq.*, 42 U.S.C. 130.

20. Add a parenthetical note following § 1357.15 to read as follows:

§ 1357.15 Comprehensive child and family services plan requirements.

* * * * *

(This requirement has been approved by the Office of Management and Budget under OMB Control Number 0980–0047. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.)

21. Add a parenthetical note following § 1357.16 to read as follows:

§ 1357.16 Annual progress and services reports.

* * * * *

(This requirement has been approved by the Office of Management and Budget under OMB Control Number 0980–0047. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.)

[FR Doc. 01–29174 Filed 11–21–01; 8:45 am]

BILLING CODE 4184–01–P

Proposed Rules

Federal Register
Vol. 66, No. 226
Friday, November 23, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–266–AD]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 Series Airplanes and Model Avro 146–RJ Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain BAE Systems (Operations) Limited Model BAe 146 and Avro 146–RJ series airplanes. This proposal would require repetitive inspections to detect cracking of the oleo strut of the nose landing gear (NLG), and corrective actions if necessary. This proposal would also provide for optional terminating action for the repetitive inspections. This action is necessary to detect and correct fatigue cracking of the oleo strut of the NLG, which could result in failure of the NLG. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by December 24, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket 2000–NM–266–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–266–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.,* reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket 2000–NM–266–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket 2000–NM–266–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, notified the FAA that an unsafe condition may exist on certain BAE Systems (Operations) Limited Model BAe 146 and Avro 146–RJ series airplanes. A nose landing gear (NLG) undergoing fatigue testing was found to have a fatigue crack at the top of the oleo bore, with resulting loss of oil and loss of strength. This condition, if not detected and corrected, could result in failure of the NLG.

Explanation of Relevant Service Information

The manufacturer has issued BAE Systems Service Bulletin SB.32–158, dated June 2, 2000, which describes procedures for repetitive non-destructive test (NDT) ultrasonic inspections to detect cracking of the bore of the NLG oleo, and modification of any cracked NLG oleo. The CAA classified this service bulletin as mandatory and issued British airworthiness directive 002–06–2000 to ensure the continued airworthiness of these airplanes in the United Kingdom.

The BAE Systems service bulletin refers to Messier-Dowty Service Bulletin 146–32–149, including Appendix A, dated April 17, 2000, as an additional source of service information for accomplishment of the inspection.

The manufacturer has also issued BAE Systems Service Bulletin SB.32–159–70668ABC, dated June 14, 2000, which describes procedures for having the modification of the NLG oleo strut performed. The modification would eliminate the need for repetitive

inspections. The modification consists of blending and shot peening of the oleo bore of the NLG to restore its expected life.

FAA's Conclusions

These airplane models are manufactured in the United Kingdom and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in BAE Systems Service Bulletin SB.32–158, dated June 2, 2000. This proposed AD also would provide for optional terminating action for the repetitive inspections. The optional terminating action, if accomplished, would terminate the repetitive inspection requirements of this AD.

Operators should note that, to be consistent with the findings of the CAA, the FAA has determined that the repetitive inspections proposed by this AD can be allowed to continue in lieu of accomplishment of a terminating action. In making this determination, the FAA considers that, in this case, long-term continued operational safety will be adequately ensured by accomplishing the repetitive inspections to detect cracking before it represents a hazard to the airplane.

Cost Impact

The FAA estimates that 60 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $3,600, or $60 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

BAE Systems (Operations) Limited (Formerly British Aerospace Regional Aircraft): Docket 2000–NM–266–AD.

Applicability: Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes, certificated in any category, as listed in BAE Systems Service Bulletin SB.32–158, dated June 2, 2000, except those on which Messier-Dowty Modification AC12248 has been installed.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct fatigue cracking of the oleo strut of the nose landing gear (NLG), which could result in failure of the nose landing gear (NLG), accomplish the following:

Inspection

(a) Perform an ultrasonic inspection to detect cracking of the oleo strut of the NLG, in accordance with BAE Systems Service Bulletin SB.32–158, dated June 2, 2000, according to the applicable time schedule specified in paragraphs (a)(1), (a)(2), and (a)(3) of this AD. Thereafter, repeat the inspection at least every 2,500 landings, until the actions specified by paragraph (c) of this AD have been performed.

(1) For NLGs identified in paragraph D.(3) of BAE Systems Service Bulletin SB.32–158, dated June 2, 2000: Inspect before the NLG accumulates 2,500 landings after accomplishment of the initial inspection specified by Messier-Dowty Service Bulletin 146–32–149, or within 30 days after the effective date of this AD, whichever occurs later.

(2) For NLGs having part number 201138002, serial numbers M–DG–0158 to M–DG–0168 inclusive, as identified in paragraph D.(4) of BAE Systems Service Bulletin SB.32–158, dated June 2, 2000: Inspect before the NLG accumulates 20,000 total landings, or within 500 flight cycles after the effective date of this AD, whichever occurs later.

(3) For NLGs other than those identified in paragraph (a)(1) or (a)(2) of this AD: Inspect before the NLG accumulates 8,000 total landings, or within 500 landings after the effective date of this AD, whichever occurs later.

Corrective Actions

(b) If any crack is found during any inspection required by this AD: Before further flight, replace the oleo strut of the NLG with a new or serviceable strut in accordance with BAE Systems Service Bulletin SB.32–158, dated June 2, 2000.

Optional Terminating Action

(c) Modification of the NLG in accordance with BAE Systems Service Bulletin SB.32–159–70668ABC, dated June 14, 2000, terminates the repetitive inspections required by this AD.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in British airworthiness directive 002–06–2000.

Issued in Renton, Washington, on November 15, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29196 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–143–AD]

RIN 2120–AA64

Airworthiness Directives; Short Brothers Model SD3–60, SD3–60 SHERPA, and SD3–SHERPA Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Short Brothers Model SD3–60, SD3–60 SHERPA, and SD3–SHERPA series airplanes. This proposal would require a one-time inspection of the two power cables to the heated windshield to detect inadequate clearance, chafing, and inadequate support. This proposal would also require corrective action, if necessary, including increasing the clearance, providing additional support, re-routing, and replacing power cables, as applicable. This action is necessary to prevent discrepancies of the two power cables to the heated windshield from causing an electrical short circuit with possible smoke and fire in the cockpit. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by December 24, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket Number 2001–NM–143–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain ''Docket Number 2001–NM–143–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Short Brothers, Airworthiness & Engineering Quality, P.O. Box 241, Airport Road, Belfast BT3 9DZ, Northern Ireland. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington, 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–143–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket Number 2001–NM–143–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, notified the FAA that an unsafe condition may exist on all Short Brothers Model SD3–60, SD3–60 SHERPA, and SD3–SHERPA series airplanes. The CAA advises that operators have reported finding discrepancies of the power cables to the heated windshields. This condition, if not corrected, could cause an electrical short circuit with possible smoke and fire in the cockpit.

Explanation of Relevant Service Information

The manufacturer has issued Short Brothers Service Bulletins SD3 SHERPA–30–2 (for Model SD3 Sherpa series airplanes); SD360 SHERPA–30–2 (for Model SD360 Sherpa series airplanes); and SD360–30–26 (for Model SD360 series airplanes), all dated April 2, 2001. Each service bulletin describes procedures for a general visual

inspection of the power cables to the heated windshield for inadequate clearance, chafing, and inadequate support. Each service bulletin also describe procedures for corrective action, if necessary, including increasing the clearance or providing additional support for the power cables, re-routing a lightly-chafed power cable, and replacing a more heavily chafed power cable with a new power cable, as applicable. Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition. The CAA classified these service bulletins as mandatory and issued British airworthiness directive 001–004–2001 to ensure the continued airworthiness of these airplanes in the United Kingdom.

FAA's Conclusions

These airplane models are manufactured in the United Kingdom and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type designs registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletins described previously.

Cost Impact

The FAA estimates that 78 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspection of the power cables to the heated windshield, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $4,680, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Short Brothers PLC: Docket 2001–NM–143–AD.

Applicability: All Model Short Brothers Model SD3–60, SD3–60 SHERPA, and SD3–SHERPA series airplanes; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent discrepancies of the two power cables to the heated windshield from causing an electrical short circuit with possible smoke and fire in the cockpit, accomplish the following:

Inspection and Corrective Action, If Necessary

(a) Within 90 days after the effective date of this AD: Perform a general visual inspection of the power cables to the heated windshield to detect inadequate clearance, chafing, and inadequate support, in accordance with Short Brothers Service Bulletin SD3 SHERPA–30–2 (for Model SD3 Sherpa series airplanes); SD360 SHERPA–30–2 (for Model SD360 Sherpa series airplanes); or SD360–30–26 (for Model SD360 series airplanes), all dated April 2, 2001, as applicable. If the general visual inspection finds no evidence of chafing and finds that clearance and support of the power cables are adequate: No further action is needed.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(b) If the general visual inspection required by paragraph (a) of this AD finds no evidence of chafing, but finds that clearance or support of the power cables are not adequate: Prior to further flight, increase the clearance or provide additional support of the power cables, in accordance with Short Brothers Service Bulletin SD3 SHERPA–30–2 (for Model SD3 Sherpa series airplanes); SD360 SHERPA–30–2 (for Model SD360 Sherpa series airplanes); or SD360–30–26 (for Model SD360 series airplanes), all dated April 2, 2001, as applicable.

(c) If the general visual inspection required by paragraph (a) of this AD finds evidence of chafing, but there is no damage to the outer nylon protective coating with exposure of the glass fiber braid: Prior to further flight, re-

route the power cables, in accordance with Short Brothers Service Bulletin SD3 SHERPA–30–2 (for Model SD3 Sherpa series airplanes); SD360 SHERPA–30–2 (for Model SD360 Sherpa series airplanes); or SD360–30–26 (for Model SD360 series airplanes), all dated April 2, 2001, as applicable.

(d) If the general visual inspection required by paragraph (a) of this AD finds evidence of chafing, and there is damage to the outer protective covering with exposure of the glass fiber braid: Prior to further flight, replace the damaged power cable with new cable, in accordance with Short Brothers Service Bulletin SD3 SHERPA–30–2 (for Model SD3 Sherpa series airplanes); SD360 SHERPA–30–2 (for Model SD360 Sherpa series airplanes); or SD360–30–26 (for Model SD360 series airplanes), all dated April 2, 2001, as applicable.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in British airworthiness directive 001–04–2001.

Issued in Renton, Washington, on November 15, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29195 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–252–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319 Series Airplanes and A320–200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Model A319 series airplanes and A320–200 series airplanes. This proposal would require repetitive inspections to detect loose or missing rivets in specified areas of the door frames of the overwing emergency exits and corrective action, if necessary. This proposal would also require measurement of the grip length of all rivets in the specified areas and corrective action, if necessary, which would terminate the repetitive inspections. This action is prompted by mandatory continuing airworthiness information from a foreign airworthiness authority. This action is necessary to detect and correct loose or missing rivets or discrepant rivets, which could lead to reduced structural integrity of the overwing emergency exit door frames. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by December 24, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket Number 2001–NM–252–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–252–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–252–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket Number 2001–NM–252–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus A319 series airplanes and A320–200 series airplanes. The DGAC advises that one operator reported finding a loose rivet at a corner of the door frame of an

overwing emergency exit during normal maintenance. Investigation of other airplanes revealed that some rivets in certain areas of the door frames had grip lengths which were slightly out of tolerance. If not corrected, rivets in specified areas of the door frames of the overwing emergency exits, which are loose or missing or have the wrong grip length, could lead to reduced structural integrity of the door frames.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A320–53–1147, dated September 22, 2000, which describes procedures for repetitive detailed visual inspections of specified areas of the door frame of the overwing emergency exits for loose or missing rivets and corrective action, if necessary. The service bulletin also describes procedures for measurement of the grip length of all rivets in the specified areas and corrective action, if necessary. The corrective actions include inspecting rivet holes for cracks, opening up certain rivet holes, repairing certain rivet holes, and installing new rivets. Measurement of the grip length of all rivets in all specified areas and corrective action, if necessary, eliminates the need for the repetitive inspections. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive 2001–241(B), dated June 27, 2001, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences between Proposed Rule and Service Bulletin

Airbus Service Bulletin A320–53–1147, dated September 22, 2000, specifies that, if a second rotating probe inspection reveals cracks at any rivet holes, the operator is to contact the manufacturer for further instructions. The proposed rule would require that, if such cracks are detected, the operator is to repair them in accordance with a method approved by the FAA or the DGAC or its delegated agent.

Cost Impact

The FAA estimates that 168 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $10,080, or $60 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 2001–NM–252–AD.

Applicability: Model A319 series airplanes and A320–200 series airplanes, as listed in Airbus Service Bulletin A320–53–1147, dated September 22, 2000; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct rivets in specified areas of the door frames of the overwing emergency exits which are loose or missing or which have the wrong grip length, which could lead to reduced structural integrity of the door frames, accomplish the following:

Inspection and Measurement

(a) Within 3,500 flight cycles after the effective date of this AD: Conduct a detailed visual inspection of the specified areas of the door frames of the overwing emergency exits for loose or missing rivets, in accordance with Part B of the Accomplishment Instructions and Figure 5 of Airbus Service Bulletin A32053–1147, dated September 22, 2000. If no loose or missing rivets are found,

repeat the detailed visual inspection and the measurement at intervals not to exceed 3,500 flight cycles until the requirements of paragraph (d) have been accomplished.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Corrective Action

(b) If the inspection required by paragraph (a) of this AD reveals that there are loose or missing rivets: Prior to further flight, accomplish the requirements of either paragraph (b)(1) or (b)(2) of this AD.

(1) Measure the grip length of all rivets in the specified areas in which the loose or missing rivets were detected and perform corrective action (e.g., inspecting rivet holes for cracks, opening up rivet holes, repairing cracks at rivet holes, and installing new rivets) as applicable, in accordance with Part C of the Accomplishment Instructions and Figure 5 of Airbus Service Bulletin A320–53–1147, dated September 22, 2000, except as specified in paragraph (c) of this AD. Repeat the detailed visual inspection required by paragraph (a) of this AD at intervals not to exceed 3,500 flight cycles until the requirements of paragraph (d) have been accomplished.

(2) Measure the grip length of all rivets in all specified areas and perform corrective action (e.g., inspecting rivet holes for cracks, opening up rivet holes, repairing cracks at rivet holes, and installing new rivets) as applicable, in accordance with Part C of the Accomplishment Instructions and Figure 5 of Airbus Service Bulletin A320–53–1147, dated September 22, 2000, except as specified in paragraph (c) of this AD.

(c) If Airbus Service Bulletin A320–53–1147, dated September 22, 2000 recommends contacting the manufacturer for instructions concerning certain repairs, perform those repairs in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate or by the Direction Générale de l'Aviation Civile (DGAC) or its delegated agent. For a repair method to be approved by the Manager, International Branch, ANM–116, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

Terminating Action

(d) Prior to the accumulation of 24,000 total flight cycles or within 3,500 flight cycles after the effective date of this AD, whichever occurs later: Accomplish the requirements of paragraph (b)(2) of this AD. Accomplishment of paragraph (b)(2) of this AD constitutes terminating action for the purpose of this AD.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 2001–241(B), dated June 27, 2001.

Issued in Renton, Washington, on November 15, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29194 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–338–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of two existing airworthiness directives (AD), applicable to certain Airbus Model A319, A320, and A321 series airplanes. The first AD currently requires removing the existing forward pintle nut and cross bolt on the main landing gear (MLG), and installing a new nylon spacer and cross bolt and nut. The second AD currently requires repetitive inspections for discrepancies of the lock bolt for the pintle pin on the MLG, follow-on corrective actions if necessary, and retorquing of the forward pintle pin lock bolt for certain airplanes. That AD also provides for an optional terminating action. This action would cancel the requirements of the first AD, continue the requirements of the second AD, and require the previously optional terminating action that was provided for in the second AD. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent a rotated, damaged, or missing lock bolt, which could result in disengagement of the pintle pin from the pintle fitting bearing, and consequent collapse of the MLG during landing.

DATES: Comments must be received by December 24, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–338–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–338–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

• Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

• For each issue, state what specific change to the proposed AD is being requested.

• Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–338–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–338–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On May 9, 1996, the FAA issued AD 96–10–18, amendment 39–9625 (61 FR 24690, May 16, 1996), applicable to certain Airbus Model A320–111, –211, –212, and –231 series airplanes, to require removing the existing forward pintle nut and cross bolt on the main landing gear (MLG) and installing a new nylon spacer and cross bolt and nut. That action was prompted by results of fatigue testing which revealed that the cross bolt and nut in the forward pintle pin of the MLG were damaged due to fatigue cracking. The requirements of that AD are intended to prevent such fatigue cracking, which could result in collapse of the MLG.

On May 16, 2000, the FAA issued AD 2000–10–16, amendment 39–11740 (65 FR 34059, May 26, 2000), to require repetitive inspections for discrepancies of the lock bolt for the pintle pin on the MLG; follow-on corrective actions, if necessary; and retorquing of the forward pintle pin lock bolt for certain airplanes. That AD also provides for an optional terminating action for the requirements of the AD. That action was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The requirements of that AD are intended to detect and correct a rotated, damaged, or missing lock bolt, which could result in disengagement of the pintle pin from the pintle fitting bearing, and consequent collapse of the MLG during landing. In the ''Comment Received'' section of that AD, the FAA stated that it may consider further rulemaking if a determination is made at a later date that the terminating modification should be mandated.

Actions Since Issuance of Previous Rules

Since the issuance of AD 96–10–18 and AD 2000–10–16, the Direction Generale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, has issued French airworthiness directive 2000–428–153(B), Revision 1, dated November 29, 2000, to continue to require the repetitive inspections of the lock bolt for the pintle pin on the MLG and follow-on corrective actions, and to mandate the optional terminating action modification identified in AD 2000–10–16.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A320–32–1213, Revision 02, dated February 9, 2001, which describes procedures for modification of the pintle pin attachment of both the left and right MLG to incorporate a dual lock bolt configuration. Modification includes a detailed visual inspection of the pintle pin lock bolts to ensure that the bolts are in proper position and are not broken, and repair if necessary; and removal and installation of the lock bolts. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive 2000–428–153(B), Revision 1, dated November 29, 2000, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would supersede AD 2000–10–16, to continue to require repetitive inspections of the lock bolt for the pintle pin on the MLG, follow-on corrective actions if necessary, and retorquing of the forward pintle pin lock bolt for certain airplanes. This proposed AD also would add a requirement for accomplishment of the terminating action modification in accordance with the service bulletin described previously, which would constitute terminating action for the repetitive inspection requirements of the AD. In addition, the proposed AD would supersede AD 96–10–18, to cancel the requirements of that AD.

Differences Between Proposed Rule and Foreign Airworthiness Directive

The proposed AD would differ from the parallel French airworthiness directive in that it would not require accomplishment of Airbus Service Bulletin A320–32–1119, followed by repetitive inspections, as an interim action alternative to Airbus Service Bulletin A320–32–1213, unless it is specifically required to correct a discrepancy found during inspection.

Cost Impact

There are approximately 341 airplanes of U.S. registry that would be affected by this proposed AD.

The actions that are currently required by AD 2000–10–16 take approximately 2 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $120 per airplane, per inspection cycle.

The new action that is proposed in this AD action would take approximately 3 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $540 per airplane. Based on these figures, the cost impact of the proposed new requirements of this AD

on U.S. operators is estimated to be $245,520, or $720 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendments 39–11740 (65 FR 34059, May 26, 2000), and 39–9625 (61 FR 24690, May 16, 1996) and by adding a new airworthiness directive (AD), to read as follows:

Airbus Industrie: Docket 2000–NM–338–AD. Supersedes AD 2000–10–16, Amendment 39–11740, and AD 96–10–18, Amendment 39–9625.

Applicability: Model A319, A320, and A321 series airplanes, certificated in any category, except those on which Airbus Service Bulletin A320–32–1213, dated March 21, 2000 (reference Airbus Modification 28903 or 30044) has been accomplished.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a rotated, damaged, or missing lock bolt, which could result in disengagement of the pintle pin from the pintle fitting bearing, and consequent collapse of the main landing gear (MLG) during landing, accomplish the following:

Note 2: Paragraphs (a) and (b) of this AD repeat the actions that were previously mandated by AD 2000–10–16. The intent of including these paragraphs is to ensure that the currently-required repetitive inspections continue to be accomplished until the terminating modifications are installed.

Restatement of Requirements of AD 2000–10–16

Inspection

(a) Perform a detailed visual inspection to detect discrepancies (rotation, damage, and absence) of the lock bolt for the pintle pin on the MLG, in accordance with Airbus All Operator Telex (AOT) 32–17, Revision 01, dated November 6, 1997; Airbus Service Bulletin A320–32–1187, dated June 17, 1998; or Airbus Service Bulletin A320–32–1187, Revision 01, dated February 17, 1999; at the latest of the times specified in paragraphs (a)(1), (a)(2), and (a)(3) of this AD. If any discrepancy is detected, prior to further flight, perform corrective actions, as applicable, in accordance with the AOT or service bulletin. Repeat the inspection thereafter at intervals not to exceed 1,000 flight cycles or 15 months, whichever occurs first, unless the terminating action of paragraph (c) of this AD is accomplished. After June 30, 2000 (the effective date of AD 2000–10–16, amendment 39–11740), only Airbus Service Bulletin A320–32–1187, Revision 01, dated February 17, 1999, shall be used for compliance with this paragraph.

(1) Within 30 months since the airplane's date of manufacture or prior to the accumulation of 2,000 total flight cycles, whichever occurs first.

(2) Within 15 months or 1,000 flight cycles after the last gear replacement or accomplishment of Airbus Service Bulletin A320–32–1119, dated June 13, 1994, whichever occurs first.

(3) Within 500 flight cycles after August 12, 1998 (the effective date of AD 98–14–11, amendment 39–10644).

Note 3: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

One-time Follow-on Actions

(b) For airplanes on which the actions described in paragraph 2.B.(2)(c) of Airbus Service Bulletin A320–32–1187, Revision 01, dated February 17, 1999, have not been accomplished: At the time of the initial inspection or the next repetitive inspection required by paragraph (a) of this AD, perform the applicable one-time follow-on actions (including retorquing the forward pintle pin lock bolt and applying sealant to the head of the lock bolt), in accordance with section 2.B.(2)(c) of the Accomplishment Instructions of Airbus Service Bulletin A320–32–1187, Revision 01, dated February 17, 1999.

New Actions Required by This AD

Terminating Modification

(c) Within 5 years from the effective date of this AD, or at the next MLG overhaul, whichever occurs later, modify the forward pintle pin cross bolt on both the left and right MLG (including a detailed visual inspection to ensure that the bolts are in proper position and are not broken, and repair if necessary; and removal and installation of the lock bolts), in accordance with Airbus Service Bulletin A320–32–1213, Revision 02, dated February 9, 2001. This modification constitutes terminating action for the requirements of this AD.

Note 4: Accomplishment of the actions required in paragraph (c) of this AD, prior to the effective date of this AD, in accordance with Airbus Service Bulletin A320–32–1213, dated March 21, 2000, or Revision 01, dated November 15, 2000, is considered acceptable for compliance with paragraph (c) of this AD.

Alternative Methods of Compliance

(d)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall

submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

(2) Alternative methods of compliance, approved previously in accordance with AD 2000–10–16, amendment 39–11740, are approved as alternative methods of compliance with this AD.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Manager, International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 6: The subject of this AD is addressed in French airworthiness directive 2000–428–153(B), Revision 1, dated November 29, 2000.

Issued in Renton, Washington, on November 15, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29193 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–CE–39–AD]

RIN 2120–AA64

Airworthiness Directives; Pilatus Britten-Norman Limited BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all Pilatus Britten-Norman Limited (Pilatus Britten-Norman) BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes. This proposed AD would require you to repetitively inspect certain oleo attachment brackets for cracks and replace any cracked bracket found during any inspection. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. The actions specified by this proposed AD are intended to detect and correct cracked oleo attachment brackets. Such a condition could cause the attachment bracket to fail, which could result in detachment of the main landing gear.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before December 21, 2001.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–CE–39–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

You may get service information that applies to this proposed AD from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone: +44 (0) 1983 872511; facsimile: +44 (0) 1983 873246. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are there any specific portions of this proposed AD I should pay attention to? The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How can I be sure FAA receives my comment? If you want FAA to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2001–CE–39–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What events have caused this proposed AD? The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, notified FAA that an unsafe condition may exist on all BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes. The United Kingdom CAA reports five occurrences of failure of the oleo attachment bracket, part number (P/N) NB–40–0075. This bracket is the main attachment point for the main landing gear. The CAA determined that the cause for failure of these brackets is the current design of the part.

What are the consequences if the condition is not corrected? Cracked oleo attachment brackets, if not detected and corrected, could fail and detach from the main landing gear.

Is there service information that applies to this subject? Pilatus Britten-Norman has issued B–N Service Bulletin Number SB 273, Issue 2, dated January 12, 2000.

What are the provisions of this service information? The service bulletin includes procedures for:

—Repetitively inspecting the oleo attachment brackets, P/N NB–40–0075, for cracks; and

—Replacing any cracked attachment bracket found during any inspection.

What action did the CAA take? The CAA classified this service bulletin as mandatory and issued CAA AD Number 005–09–2000, not dated, in order to ensure the continued airworthiness of these airplanes in the United Kingdom.

Was this in accordance with the bilateral airworthiness agreement? These airplane models are manufactured in the United Kingdom and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Pursuant to this bilateral airworthiness agreement, the United Kingdom CAA has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of this Proposed AD What has FAA decided? The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that:

—The unsafe condition referenced in this document exists or could develop on all Pilatus Britten-Norman BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes of the same type design that are on the U.S. registry;
—The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and
—AD action should be taken in order to correct this unsafe condition.

What would this proposed AD require? This proposed AD would require you to repetitively inspect the oleo attachment brackets, P/N NB–40–0075, for cracks and replace any cracked bracket found during any inspection.

Are there differences between this proposed AD, the service information, and the CAA AD? The service information requires repetitive inspections at intervals not to exceed 500 hours time-in-service (TIS) or 1,200 landings, whichever occurs first. This proposed AD and the CAA AD require repetitive inspections at intervals not to exceed 100 hours TIS or 200 landings, whichever occurs first, in order to ensure that the unsafe condition specified in this proposed AD does not go undetected for a long period of time.

Is there a modification I can incorporate instead of repetitively inspecting the oleo attachment brackets? The FAA has determined that long-term continued operational safety would be better assured by design changes that remove the source of the problem rather than by repetitive inspections or other special procedures. With this in mind, FAA will continue to work with Pilatus Britten-Norman.

The manufacturer is now in the process of changing the design of the oleo attachment bracket, P/N NB–40–0075. The design change will eliminate the need for the repetitive inspection. The newly designed part will be introduced by a new modification that will be included as part of Issue 3 of Service Bulletin SB 273.

Cost Impact

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects 126 airplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the proposed inspections:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
3 workhours × $60 per hour = $180	No cost for parts.	$180.	$180 × 126 = $22,680.

We estimate the following costs to accomplish any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of airplanes that may need such repair/replacement:

Labor cost	Parts cost	Total cost per airplane
12 workhours × $60 per hour = $720	$370.	$720 + $370 = $1,090.

Regulatory Impact

Would this proposed AD impact various entities? The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed action (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Pilatus Britten-Norman LTD.: Docket No. 2001–CE–39–AD

(a) *What airplanes are affected by this AD?* This AD affects Models BN–2, BN–2A, BN–2A–2, BN–2A–3, BN–2A–6, BN–2A–8, BN–2A–9, BN–2A–20, BN–2A–21, BN–2A–26, BN–2A–27, BN–2B–20, BN–2B–21, BN–2B–26, BN–2B–27, BN–2T, BN–2T–4R, BN2A MK. III, BN2A MK. III–2, and BN2A MK. III–3 airplanes, all constructor numbers, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct cracked oleo attachment brackets. Such a condition could cause the attachment bracket to fail, which could result in detachment of the main landing gear.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect, visually or using 10× magnifying glass, the oleo attachment brackets, part number (P/N) NB–40–0075, for cracks.	Within the next 25 hours time-in-service (TIS) or 50 landings, whichever occurs first, after the effective date of this AD, and thereafter at intervals not to exceed 100 hours TIS or 2000 landings, whichever occurs first.	In accordance with B–N Service Bulletin Number SB 273, Issue 2, dated January 12, 200.
(2) If cracks are found during any inspection required by this AD, replace the bracket with another oleo attachment bracket, P/N NB–40–0075.	Prior to further flight after the inspection(s) required in paragraph (d)(1) of this AD in which the crack is found. Repetitively inspect thereafter at intervals not to exceed 100 hours TIS or 200 landings, whichever occurs first.	In accordance with B–N Service Bulletin Number SB 273, Issue 2, dated January 12, 2000, and the applicable maintenance manual.
(3) Do not install any oleo attachment bracket, P/N NB–40–0075 (or FAA-approved equivalent part number), unless it has been inspected as required in paragraph (d)(1) of this AD and determined to be airworthy.	As of the effective date of this AD.	Not applicable.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone: +44 (0) 1983 872511; facsimile: +44 (0) 1983 873246. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in United Kingdom CAA AD 005–09–2000, not dated.

Issued in Kansas City, Missouri, on November 14, 2001.

Michael K. Dahl,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29192 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NE–25–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney 4000 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to adopt a new airworthiness directive (AD) that is applicable to Pratt & Whitney (PW) PW4090, PW4090–3, PW4074D, PW4077D, PW4090D, and PW4098 turbofan engines with 15th stage high pressure compressor (HPC) disks having certain part numbers (P/N's). This proposal would require initial and repetitive borescope inspections of 15th stage HPC disks for cracks in the knife edges, eddy current inspections (ECI's) of blade loading slots if required, and removal of cracked disks. In addition, this proposal would require the removal from service of these P/N disks, at a new lower cyclic life limit. This proposal is prompted by two reports of 15th stage HPC disks with cracks in the outer rim front rail of the blade loading slots, and in the front forward and middle knife edges. The actions specified by the proposed AD are intended to prevent 15th stage HPC disk failures from cracks, which could result in an uncontained engine failure.

DATES: Comments must be received by January 22, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–25–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location, by appointment, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: *9-ane-adcomment@faa.gov.* Comments sent via the Internet must contain the docket number in the subject line. The service information referenced in the proposed rule may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–6600, fax (860) 565–4503. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and

Propeller Directorate, 12 New England Executive Park; telephone (781) 238–7747, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NE–25–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–25–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

In March of 2001, the FAA received two reports from the manufacturer of two factory engines with cracks in the 15th stage HPC disk blade loading slot outer rim front rail, and in the front forward and middle knife edges. The manufacturer's investigation results revealed that the crack initiations were caused by thermo-mechanical fatigue. Due to these investigation results, this proposal would require initial borescope inspections of 15th stage HPC disks P/N 56H015 and 57H715 for cracks in the knife edges and blade loading slots, eddy current inspections (ECI's) within 25 cycles-in-service from the time of borescope inspection of blade loading slots if required, and removal of cracked disks. Repetitive borescope inspections at intervals of no more than 1,000 cycles-in-service since last inspection are also required. In addition, this proposal would require the removal from service of these P/N disks, at a new lower cyclic life limit of 8,000 cycles-since-new (CSN). The actions specified by the proposed AD are intended to prevent 15th stage HPC disk failures from cracks, which could result in an uncontained engine failure. Currently there is no terminating action for the repetitive inspections due to cracking of 15th stage HPC disks, P/N's 56H015 and 57H715. This condition, if not corrected, could result in disk rupture and uncontained engine failure.

Manufacturer's Service Information

The FAA has reviewed and approved the technical contents of PW Service Bulletin (SB) PW4G–112–A72–242, dated May 1, 2001 that describes procedures for initial and repetitive borescope inspections of 15th stage HPC disks for cracks in the front forward and middle knife edges, ECI's of front rail of the blade loading slots that have suspect cracks, within 25 cycles-in-service from time of initial borescope inspection, and the removal of cracked disks. In addition, the SB requires the removal from service of disks at a new lower cyclic life limit of 8,000 hours CSN.

Differences Between This AD and the Manufacturer's Service Information

Pratt & Whitney (PW) SB PW4G–112–A72–242, dated May 1, 2001, requires that for disks removed from engines in a maintenance facility for HPC rotor maintenance, that includes rotor tip grinding, the inspection specified in Engine Cleaning, Inspection, and Repair Manual, Chapter/Section 72–35–92, Inspection/Check-02 must be done on disks with 2,000 CSN or less. The SB also requires that disks removed from engines, with more than 2,000 CSN be replaced with a serviceable disk. PW has informed the FAA that to help reduce the operators' cost of replacing disks, PW may supply replacement disks at no cost, to be installed at the time disks with more than 2,000 CSN are removed for maintenance. This proposed AD addresses only inspections, replacement, and new cyclic life limit of installed disks.

FAA's Determination of an Unsafe Condition and Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other PW PW4090, PW4090–3, PW4074D, PW4077D, PW4090D, and PW4098 turbofan engines of the same type design with 15th stage HPC disks P/N's 56H015 and 57H715, the proposed AD would require initial and repetitive borescope inspections of 15th stage HPC disks for cracks in the front forward and middle knife edges, ECI's of blade loading slots that have suspect cracks or cracks, within 25 cycles-in-service from time of initial borescope inspection, and the removal of cracked disks. In addition, the proposed AD would require the removal from service of disks at a new lower cyclic life limit of 8,000 hours CSN.

Economic Analysis

There are approximately 160 PW4090, PW4090–3, PW4074D, PW4077D, PW4090D, and PW4098 turbofan engines of the affected design in the worldwide fleet. The FAA estimates that 70 engines installed on airplanes of U.S. registry would be affected by this proposed AD. The FAA also estimates that it would take approximately 2.5 work hours per engine to accomplish an initial borescope inspection, and that the average labor rate is $60 per work hour. Required parts for a borescope inspection would cost approximately $9 per engine. Based on these figures, the total cost effect for the initial borescope inspection for U.S. operators is estimated to be $11,130. Assuming that all 70 engines would require 15th stage HPC disk replacement, and that a replacement disk costs approximately $65,000, the total disk cost effect of the proposed AD on U.S. operators is estimated to be $4,550,000.

Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this

action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Pratt & Whitney: Docket No. 2001–NE–25–AD.

Applicability: This airworthiness directive (AD) is applicable to Pratt & Whitney (PW) PW4090, PW4090–3, PW4074D, PW4077D, PW4090D, and PW4098 turbofan engines with 15th stage high pressure compressor (HPC) disks part numbers (P/N's) 56H015 or 57H715. These engines are installed on, but not limited to Boeing 777 airplanes.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent 15th stage HPC disk failures from cracks, which could result in an uncontained engine failure, do the following:

Initial Inspection

(a) Perform an initial inspection for cracks in the front rail of the blade loading slots and front forward and middle knife edges of the 15th stage HPC disk, and replace disk in accordance with paragraphs 1.A. through 1.E.(4) of, ''For Engines Installed on Aircraft''; or paragraphs 2.A. through 2.E.(4) of, ''For Engines Removed From the Aircraft'', of the Accomplishment Instructions of PW Service Bulletin PW 4G–112–A72–242, dated May 1, 2001, and the following Table 1:

TABLE 1.—15TH STAGE HPC DISK INITIAL INSPECTION

Action	If:	Then:
(1) Borescope-inspect disk, within 4,600 cycles-since-new (CSN) or before 90 days after the effective date of this AD, whichever occurs later..	(i) Borescope inspection shows a crack in any knife edge area..	Replace the disk with a serviceable disk before further flight.
.....	(ii) Borescope inspection shows a suspect crack in any loading slot..	Perform an eddy current inspection (ECI) to confirm crack within the next 25 cycles-in-service (CIS), and if cracked replace with a servicable disk before further flight.

Repetitive Inspections

(b) Perform repetitive inspections in accordance with the inspection procedures in paragraph (a) of this AD at intervals of no more than 1,000 CIS since the last inspection.

New Cyclic Life Limit

(c) This AD establishes a new cyclic life limit for 15th stage HPC disks P/N's 56H015 and 57H715 of 8,000 cycles-since-new (CSN). Thereafter, except as provided in paragraph (d) of this AD, no alternative cyclic life limit may be approved for 15th stage HPC disks P/N's 56H015 and 57H715.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(e) Special flight permits may be issued in accordance §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on November 14, 2001.

Donald E. Plouffe,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–29191 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NE–27–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT9D–59A, –70A, –7Q, and –7Q3 Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to adopt a new airworthiness directive (AD) that is applicable to Pratt & Whitney (PW) JT9D–59A, –70A, –7Q, and –7Q3 turbofan engines. This proposal would require fluorescent penetrant inspection of the high pressure turbine (HPT) second stage airseal knife edges for cracks, each time the airseal is accessible. This proposal is prompted by reports of cracks found in the knife edges of HPT second stage airseals during HPT disassembly. The actions specified by the proposed AD are intended to prevent failure of HPT second stage airseals due to cracks in the knife edges, which if not detected could result in uncontained engine failure and damage to the airplane.

DATES: Comments must be received by January 22, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–27–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location, by

appointment, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays. Comments may also be sent via the Internet using the following address: ''*9-ane-adcomment@faa.gov*''. Comments sent via the Internet must contain the docket number in the subject line. The service information referenced in the proposed rule may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–8770; fax (860) 565–4503. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Tara Goodman, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7130, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NE–27–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–NE–27–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

The FAA has received 25 reports of cracks found in the knife edges of HPT second stage airseals, part numbers (P/N's) 5002537–01 and 807410, during HPT disassembly. To date, no failed airseal has caused an uncontained engine failure. Results from an evaluation conducted by PW reveal that engine operating temperatures and stresses in the stage 1-to-stage 2 airseal cavity are higher than anticipated. As a result, heavy rubbing and thermal mechanical fatigue in a hot compression environment are causing cracks to initiate in the rear knife edge. These cracks will propagate axially until the airseal fails. Eleven of the 25 cracked HPT second stage airseals found at overhaul were fractured through from snap to snap. This condition, if not corrected, could result in an uncontained engine failure and damage to the airplane.

Manufacturer's Service Information

The FAA has reviewed and approved the technical contents of PW service bulletin (SB) JT9D 6409, dated July 27, 2001, that describes procedures for fluorescent penetrant inspecting knife edges of HPT second stage airseals.

FAA's Determination of an Unsafe Condition and Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other PW JT9D–59A, –70A, –7Q, and –7Q3 turbofan engines of the same type design, the proposed AD would require fluorescent penetrant inspection of the knife edges of HPT second stage airseals for cracks each time the airseal is accessible. The actions would be required to be done in accordance with the SB described previously. The FAA has been informed by PW that a new design HPT second stage airseal is being developed. The FAA may revise this action to introduce the new design as terminating action.

Economic Analysis

There are approximately 564 engines of the affected design PW JT9D–59A, –70A, –7Q, and –7Q3 turbofan engines in the worldwide fleet. The FAA estimates that 176 engines installed on airplanes of U.S. registry would be affected by this proposed AD. The FAA also estimates that it would take approximately 1 work hour per engine to perform the fluorescent penetrant inspection, and that the average labor rate is $60 per work hour. Based on these figures, the total labor cost effect annually of the proposed AD on U.S. operators is estimated to be $10,560.

Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended].

2. Section 39.13 is amended by adding the following new airworthiness directive:

Pratt & Whitney: Docket No. 2001–NE–27–AD.

Applicability: This airworthiness directive (AD) is applicable to Pratt & Whitney (PW) JT9D–59A, –70A, –7Q, and –7Q3 turbofan engines. These engines are installed on, but not limited to, Airbus Indusrie A300 series, Boeing 747 series, and McDonnell Douglas DC–10 series airplanes.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent failure of high pressure turbine (HPT) second stage airseals due to cracks in the knife edges, which if not detected could result in uncontained engine failure and damage to the airplane, do the following:

Inspections

(a) Perform a fluorescent penetrant inspection of the HPT second stage airseal knife edges for cracks in accordance with Accomplishment Instructions, Paragraphs 1 through 3 of PW Service Bulletin (SB) JT9D 6409, dated July 27, 2001, each time the HPT stage 1 and stage 2 rotors are separated. Remove from service those airseals that are found cracked.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(c) Special flight permits may be issued in accordance §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on November 14, 2001.

Donald E. Plouffe,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–29190 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 136

[FRL–7106–8]

Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is extending the comment period for the proposed rule to revise and ratify its approval of several analytical test procedures measuring ''whole effluent toxicity.'' The proposed rule was published in the **Federal Register** on September 28, 2001 (66 FR 49794), and the comment period was scheduled to end on November 27, 2001. The comment period will be extended for 45 days and will now end on January 11, 2002.

DATES: Comments must be postmarked, delivered by hand, or electronically mailed on or before January 11, 2002. Comments provided electronically will be considered timely if they are submitted by 11:59 p.m. Eastern Standard Time (EST) on January 11, 2002.

ADDRESSES: Send written or electronic comments on the proposed rule (66 FR 49794) to ''Whole Effluent Toxicity (WET) Test Method Changes'' Comment Clerk (WET–IX); Water Docket (4101); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, NW., Washington, DC 20460. EPA requests that commenters submit copies of any references cited in comments. Commenters also are requested to submit an original and three copies of their written comments and enclosures. Commenters that want receipt of their comments acknowledged should include a self-addressed, stamped envelope. All written comments must be postmarked or delivered by hand. No facsimiles (faxes) will be accepted. Hand deliveries should be delivered to EPA's Water Docket at 401 M Street, SW., Room EB 57, Washington, DC 20460.

Comments may be submitted electronically to: *OW-Docket@epa.gov.* Electronic comments must be submitted as a Word Perfect 5/6/7/8 file or an ASCII file, avoiding the use of special characters and any form of encryption. Comments and data also will be accepted on disks in WordPerfect 5/6/7/8 or ASCII file format. Electronic comments may be filed online at any Federal Depository Library. All electronic comments must be identified by docket number (WET–IX). Electronic comments will be transferred into a paper version for the official record. EPA will attempt to clarify electronic comments if there is an apparent error in transmission.

A record for the proposed rulemaking (66 FR 49794) has been established under docket number WET–IX. A copy of the supporting documents cited in the proposed rule is available for review at EPA's Water Docket, East Tower Basement (Room EB 57), 401 M Street, SW., Washington, DC 20460. For access to docket materials, call (202) 260–3027 on Monday through Friday, excluding Federal holidays, between 9 a.m. and 3:30 p.m. EST to schedule an appointment.

The proposed rule (66 FR 49794) has been placed on the Internet for public review and downloading at the following location: http://www.epa.gov/fedrgstr/. Other documents referenced in the proposed rule also are available on the Internet. The final report of EPA's WET Interlaboratory Variability Study (Volumes 1 and 2) and the document titled, Proposed Changes to Whole Effluent Toxicity Method Manuals are available on the Internet at *http://www.epa.gov/waterscience/WET.*

FOR FURTHER INFORMATION CONTACT: For regulatory information regarding this notice or the proposed rule, contact Marion Kelly, Engineering and Analysis Division (4303), Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460 (e-mail: kelly.marion@epa.gov) or call (202) 260–7117. For technical information regarding the proposed rule, contact Teresa J. Norberg-King, National Health and Environmental Effects Research Laboratory, Mid-Continent Ecology Division, Office of Research and Development, U.S. Environmental Protection Agency, 6201 Congdon Boulevard, Duluth, MN 55804 (e-mail: *norberg-king.teresa@epa.gov*) or call (218) 529–5163.

SUPPLEMENTARY INFORMATION: On September 28, 2001, EPA published in the **Federal Register** (66 FR 49794) a proposed rule to ratify its approval of several whole effluent toxicity (WET) test methods, which the Agency standardized in an earlier rulemaking (60 FR 53529; October 16, 1995). The proposed rule published on September 28, 2001 also would modify the WET

test procedures to update the methods, provide minor corrections and clarifications, and address specific stakeholder concerns. The proposed changes are intended to improve the performance of WET tests, and thus increase confidence in the reliability of the results obtained using the test procedures. By proposing to revise and ratify WET test methods, EPA satisfied obligations in a settlement agreement designed to resolve litigation over the original rulemaking that standardized WET test procedures.

In the September 28, 2001 notice of proposed rulemaking, EPA requested public comment on its proposal to revise and ratify WET test methods. The 60-day public comment period established for this rule was scheduled to end on November 27, 2001. EPA received a request to extend the public comment period beyond the November 27, 2001 due date. In order to ensure that the public has an adequate opportunity to review and comment on the proposed rule, EPA is extending the comment period for an additional 45 days to January 11, 2002.

Dated: November 15, 2001.

G. Tracy Mehan, III,

Assistant Administrator for Water.

[FR Doc. 01–29270 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2134–P]

RIN 0938–AL05

Medicaid Program; Modification of the Medicaid Upper Payment Limit for Non-State Government-Owned or Operated Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would modify the Medicaid upper payment limit provisions to remove the 150 percent UPL for inpatient hospital services and outpatient hospital services furnished by non-State government-owned or operated hospitals. This proposed rule is part of this Administration's efforts to restore fiscal integrity to the Medicaid program and reduce the opportunity for abusive funding practices based on payments unrelated to actual covered Medicaid services.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 24, 2001.

ADDRESSES: In commenting, please refer to file code CMS–2134–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2134–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marge Lee, (410) 786–4361.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call Ms. Freddie Wilder at (410) 786–7195 or (410) 786–0082.

I. Background

Section 1902(a)(30)(A) of the Social Security Act (the Act) requires that Medicaid State plans have methods and procedures relating to the payment for care and services to assure that payments are consistent with efficiency, economy, and quality of care. This provision is implemented in regulations at 42 CFR part 447 that set upper payment limits (UPLs) for different types of items and services. For certain institutional providers, including hospitals, these upper payment limits apply in the aggregate to all payments to a particular class of providers, and are based on the estimated payment under Medicare payment principles.

In a final rule published on January 12, 2001 in the **Federal Register** (66 FR 3148), we revised the Medicaid upper payment limit (UPL) for inpatient and outpatient hospitals to require separate UPLs for State-owned or operated facilities, non-State government-owned or operated facilities, and privately owned and operated facilities. In that final rule, we also created an exception for payments to non-State government-owned or operated hospitals. That exception provided that the aggregate Medicaid payments to those hospitals may not exceed 150 percent of a reasonable estimate of the amount that would be paid for the services furnished by these hospitals under Medicare payment principles. At that time, we believed that there was a need for a higher UPL to apply to payments to these public hospitals because their important role in serving the Medicaid population.

Based on further analysis, we do not believe that a significant amount of the additional payments permitted under this exception is being used to further the mission of these hospitals or their role in serving Medicaid patients. The Office of the Inspector General has issued several reports demonstrating that a portion of the additional payments are being transferred directly back to the State via intergovernmental transfers and used for other purposes (which may include funding the State share of other Medicaid expenditures). Since the public hospitals are not retaining the funds available as a result of this higher UPL, those funds are neither furthering their special mission nor ensuring continued access to these facilities for the Medicaid population. Instead, the only result of the higher UPL is that the Federal government is effectively paying more than its share of net State Medicaid expenditures.

II. Provisions of the Proposed Rule

As part of this Administration's efforts to restore fiscal integrity to the Medicaid program and reduce the opportunity for abusive funding practices based on payments unrelated to actual covered Medicaid services, we propose to remove the 150 percent UPL for non-State government-owned or operated hospitals.

Under §§ 447.272(b) and 447.321(b), aggregate payments to non-State government-owned or operated facilities would be limited to a reasonable estimate of the amount that would be

paid for the services furnished by this group of facilities under Medicare payment principles. Payments under an approved State plan would be reduced to comply with this limit as of the effective date of the subsequent final rule. In addition, we would not approve any methodologies that allow payments in excess of this limit as of the effective date of the final rule. Moreover, States should note that we have issued a letter to State Medicaid Directors announcing a policy for addressing amendments submitted after the publication date of this proposed rule, which would provide for payments that exceed those permitted under this proposed rule. States cannot reasonably expect to rely on financing from such plan amendments that exceed the proposed limit as we intend to proceed with a final rule in the near future.

In § 447.272(c), we would remove the exception in paragraph (c)(1) regarding payments to non-State government-owned or operated hospitals. We would redesignate the exceptions in paragraph (c)(2) to (c)(1) and (c)(3) to (c)(2) for payments to Indian Health Services and tribal facilities and disproportionate share hospitals (subject to a separate limit on payments to disproportionate share hospitals). In § 447.321, we would revise paragraphs (b) through (d).

State payment methodologies that qualify for a transition period described in §§ 447.272(e) and 447.321(e) would continue to qualify for the same transition period. However, aggregate payments to non-State government-owned or operated hospitals during the transition period would need to be reduced to 100 percent of a reasonable estimate of the amount that would be paid for the services furnished by this group of facilities under Medicare payment principles rather than 150 percent as described in the final rule published on January 12, 2001. In §§ 447.272 and 447.321, we would redesignate paragraph (e)(2)(ii)(C)(8) regarding when a reduction begins as paragraph (e)(2)(iii). We would also redesignate paragraph (e)(2)(iii) as (e)(2)(iv).

State payment methodologies that do not qualify for a transition period must be in compliance with the 100 percent UPL for non-State government-owned or operated hospitals as of the effective date of a subsequent final rule.

We would also remove § 447.272(f)(1)(i) and (f)(1)(ii) and § 447.321(f)(1)(i) and (f)(1)(ii), which describes the reporting requirements for non-State government-owned or operated hospitals, and retain paragraph (f)(1) that describes only the reporting requirements for payments made by States in excess of the amount described in paragraph (b) of this section during the transition periods. The reporting requirements for these States would not change.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

IV. Collection of Information Requirements Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are seeking comments on these issues for the provisions discussed below:

Section 447.272 Inpatient Services: Application of Upper Payment Limits

Under paragraph (f), *Reporting requirements for payments during the transition periods,* States that are eligible for a transition period described in section 447.272(e), and that make payments that exceed the limit under section 447.272(b) must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

We estimate that there would be 57 reports filed the first year and that they would take 8 hours, for a total of 456 hours. The number of reports and corresponding burden would decrease each year.

Section 447.321 Outpatient Hospital and Clinic Services: Application of Upper Payment Limits

Under paragraph (f), *Reporting requirements for payments during the transition periods,* States that are eligible for a transition period described in section 447.321(e), and that make payments that exceed the limit under section 447.321(b), would have to report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

We estimate that there would be 31 reports filed the first year under this section and that it would take 8 hours to complete one, for a total of 248 hours. The number of reports and corresponding burden would decrease over the next 8 years.

The particular information collection requirements contained in these two sections were published in the January 12, 2001 final rule. We are proposing to revise these requirements by eliminating the reporting requirement that States report hospital expenditures up to the 150 percent UPL, consistent with its elimination in this proposed rule.

We have recently submitted an emergency request for approval of the information collection requirements associated with the January 12, 2001 final rule to OMB for review of the requirements in §§ 447.272 and 447.321. These sections have been approved by OMB under OMB number 0938–0855 through May 2002 and are now in effect. In conjunction with the development of this proposed rule, we plan to revise these reporting requirements consistent with the content of the final rule, taking all comments into account.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid, Office of Information Services, DHES, SSG, Attn: Julie Brown, CMS–2134–P, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office

Building, Washington, DC 20503, Attn: Brenda Aguilar.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this proposed rule as required by Executive Order (EO) 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). EO 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We consider this a major rule and provide an analysis below.

B. Overall Impact

The estimates provided below are based on State-reported Federal fiscal year information submitted with State plan amendments and State expenditure information, where available.

We have identified approximately 28 States with State plan amendments that may provide for payments to non-State government-owned or operated hospitals for inpatient or outpatient services in excess of the 100 percent UPL. These plans currently account for approximately $3.1 billion in Federal spending annually. This estimate is based on State-reported Federal fiscal information submitted with State plan amendments and State expenditure information, where available. In addition, we expect that, absent rulemaking, additional States would submit amendments to increase spending above the 100 percent UPL in the future. Estimates of these increased costs, both current and future, are included in the President's FY 2002 Medicaid budget baseline. Based on these budget estimates, we estimate that removing the higher UPL for non-State government-owned or operated hospitals would reduce potential Federal costs by about $9 billion over fiscal years 2002 through 2006.

C. Impact on Small Entities and Rural Hospitals

The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million to $25 million (see 65 FR 69432) or less annually. For purposes of the RFA, all hospitals are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

We believe the removal of the higher UPL proposed in this rule may have a significant impact on small entities, including rural hospitals. Although the rules published on January 12, 2001 would allow States to make higher payments to non-State government-owned or operated hospitals, States had made higher payments to these providers under the prior rules. Arguably, these hospitals may have developed a reasonable reliance on the higher payments. Nevertheless, we believe the impact of this rule will be largely mitigated due to several factors. First, payment methodologies in excess of the January 2001 final rule may qualify for one of the transition periods described in §§ 447.272(e) and 447.321(e). State payment methodologies that qualify for one of the transition periods would continue to qualify under this rule; the only difference is that payments to non-State government-owned or operated hospitals must be reduced over the transition period to a 100 percent UPL rather than a 150 percent UPL. In addition, the OIG has issued several reports demonstrating that hospitals transfer the bulk of the higher payments to the States. Since the hospitals are not retaining the funds available as a result of this higher UPL, those funds are neither furthering their special mission nor ensuring continued access to these facilities for the Medicaid population.

We invite public comments on the possible effects that this proposed rule would have on small entities in general and on small rural hospitals in particular.

D. The Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies perform an assessment of anticipated costs and benefits before proposing any rule that may result in a mandated expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by private sector, of $100 million. Because this proposed rule does not mandate any new spending requirements or costs, but rather limits aggregate payments to a group of hospitals, we do not believe it has any unfunded mandate implications.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe this proposed rule in any way imposes substantial direct compliance costs on State and local governments or preempts or supersedes State or local law.

F. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR part 447 as follows:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Amend § 447.272 as follows:

a. Revise paragraph (b).

b. Remove paragraph (c)(1).

c. Redesignate paragraph (c)(2) as (c)(1).

d. Redesignate paragraph (c)(3) as (c)(2).

e. Revise paragraph (d).

f. Revise paragraph (e)(1)(ii).

g. Redesignate paragraph (e)(2)(iii) as (e)(2)(iv).

h. Redesignate paragraph (e)(2)(ii)(C)(*8*) as paragraph (e)(2)(iii).

i. Revise paragraph (f).

§ 447.272 Inpatient services: Application of upper payment limits.

* * * * *

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of

the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

* * * * *

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b)(1) of this section by one of the following dates:

(1) *For non-State government-owned or operated hospitals*—[the effective date of the final rule].

(1) *For all other facilities*—March 13, 2001.

(e) *Transition periods*—* * *

(1) * * *

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

* * * * *

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the upper payment limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

3.Amend § 447.321 as follows:

a. Revise paragraphs (b) through (d).

b. Revise paragraph (e)(1)(ii).

c. Redesignate paragraph (e)(2)(iii) as (e)(2)(iv).

d. Redesignate paragraph (e)(2)(ii)(C)(*8*) as paragraph (e)(2)(iii).

e. Revise paragraph (f).

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

* * * * *

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(c) *Exception—Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Public Law 93–638).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b)(1) of this section by one of the following dates:

(1) *For non-State government-owned or operated hospitals*—[the effective date of the final rule].

(2) *For all other facilities*—March 13, 2001.

(e) *Transition periods*—* * *

(1) * * *

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

* * * * *

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: October 16, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 6, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–29327 Filed 11–20–01; 11:00 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[IB Docket No. 95–91; DA 01–2570]

Authorization of Satellite Digital Audio Radio Service Terrestrial Repeater Networks

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: With this document, the Federal Communications Commission seeks to augment the record concerning terrestrial repeaters in the Satellite Digital Audio Radio Service. Comments are sought on the proposals set out in the document to seek resolution of issues identified in the record that have not yet been directly addressed by commenters. The comments filed in response to this document and those currently in the record will be used to develop specific rules for the use of terrestrial repeaters in SDARS.

DATES: Comments are due December 14, 2001. Reply comments are due December 21, 2001.

ADDRESSES: Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). (*See* Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998)). Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* In completing the transmittal screen, parties responding should include their full name, mailing address, and the applicable docket number, IB Docket No. 95–91. Parties filing comments on paper must file an original and four copies of each filing. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. An additional copy of all pleadings should also be sent to Rockie Patterson, International Bureau, FCC Room 6–B524, 445 12th Street, SW., Washington, DC 20554. One copy of all comments should also be sent to the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Copies of all filings are available for public inspection and copying during regular business hours at the FCC's Reference Information Center, 445 12th Street, SW., Washington, DC, telephone 202–857–3800; facsimile 202–857–3805.

FOR FURTHER INFORMATION CONTACT: Rockie Patterson, Satellite Engineering

Branch, Satellite and Radio communication Division, International Bureau, 202–418–1183.

SUPPLEMENTARY INFORMATION: This is a summary of Report No. SPB–176, DA 01–2570, released on November 1, 2001. The full text of this document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com*.

Summary

In March 1997, the Commission adopted service rules for satellite digital audio radio service (SDARS) authorizations in the 2320–2345 MHz frequency band. (*See* 62 FR 11083 (March 11, 1997)). In conjunction with the service rules, the Commission issued a Further Notice of Proposed Rulemaking (*See* 62 FR 19095 (April 18, 1997), seeking comment on the proposed use of SDARS repeaters which some applicants intended to implement, as necessary, in urban canyons and other areas where it may be difficult to receive DARS signals transmitted by a satellite. At that time, no information was in the record on the specific operations of the SDARS repeaters and several issues concerning the licensing and regulation of the repeaters were unresolved. Since the Further Notice, the Commission has received detailed technical information on the SDARS repeaters and significant comment from the Wireless Communications Service (WCS), Multipoint Distribution Service (MDS), Instructional Television Fixed Service (ITFS) licensees and the SDARS licensees on terrestrial repeater licensing. By this document, we seek to augment the record on the specific proposals described below for the resolution of issues identified in the record that have not yet been directly addressed by commenters.

Proposals

We seek comment on an approach that defines a compensation methodology for SDARS licensees to pay for the components necessary for WCS licensees to eliminate the effects of blanketing interference to their receivers. *See* 47 CFR 27.58. We seek comment on this approach and on any variation or alternatives that commenters have proposed in this proceeding. We also include for comment various alternatives for a long-term solution to the potential blanketing interference between SDARS and WCS licensees with stations close to high power repeaters. We seek comment on provisions that would address the effect of SDARS operations on MDS and ITFS licensees. Commenters should support their views with concrete analysis and documentation.

I. Repeater Requirements

We seek comment on the sufficiency of an approach that would require SDARS repeaters to meet the following:

A. Definitions.

1. Low Power Repeaters (LPRs) are limited to an EIRP less than or equal to 2 kW.

2. High Power Repeaters (HPRs) are limited to an EIRP greater than 2 kW and less than or equal to 40 kW.

B. Authorized transmissions.

SDARS repeaters shall be used only to transmit the complete programming, and only that programming that is also transmitted by an authorized DARS satellite and in such a way that the satellite signal and the terrestrial repeater signal are received nearly simultaneously by SDARS subscriber receivers.

C. Eligibility and frequencies.

Authorization to operate SDARS repeaters is granted only to licensees of SDARS systems with operational space stations. An SDARS licensee shall locate repeater frequency assignments in the center of its exclusively licensed frequency band, with the edge of the repeater band being no less than four megahertz from the edge of the SDARS spectrum at 2320 MHz and 2345 MHz.

D. Emission limits.

1. SDARS repeater out-of-band emission levels shall comply with 47 CFR 25.202(f) within the 2320–2332.5 MHz and 2332.5–2345 MHz frequency bands.

2. Below 2320 MHz and above 2345 MHz, the power of any SDARS repeater emission shall be attenuated below the peak equivalent isotropically radiated power (P_{eirp}) within the assigned frequency band(s) of operation between 2320 MHz and 2345 MHz, measured in watts, by a factor not less than 75 + 10log (P_{eirp}) dB, where P_{eirp} is measured in watts.

3. Compliance with the previous provision is based on the use of measurement instrumentation employing a resolution bandwidth of 1 MHz or more, but at least one percent of the emission bandwidth of the fundamental emission of the transmitter, provided the measured energy is integrated over a 1 MHz bandwidth.

II. Prior Approval

We seek comment on SDARS licensees obtaining prior Commission approval to operate: (1) Any SDARS repeater that exceeds the power levels and/or proximity restrictions specified in existing international agreements with Canada and Mexico covering the use of SDARS frequency bands, except that Commission approval shall not be required for SDARS repeaters already coordinated successfully with Canada or Mexico; (2) any SDARS repeater that fails to comply with the requirements of 47 CFR 17.4 of the Commission's rules; (3) any SDARS repeater that will have significant environmental effects, as defined by 47 CFR 1.1301 through 1.1319 of the Commission's rules. We seek comment on the feasibility of this requirement.

III. Low Power Repeater (LPR) Operations

A. *LPR Operation.* We seek comment on permitting an SDARS licensee to operate an unlimited number of LPRs without prior coordination as of the effective date of the Commission Order adopting final rules governing SDARS repeaters and where prior approval is not required.

B. *Notification of LPRs to WCS, MDS/ITFS licensees.* We seek comment on imposing a notification requirement on SDARS licensees to provide notice to any WCS, MDS, or ITFS licensee that may be operating in the vicinity of an LPR brought into operation after the final SDARS rules are effective. At least 30 days prior to commencing operations from any new LPR transmitting station, or with increased power from any existing LPR up to 2 kW EIRP, the SDARS licensee shall notify all WCS, and MDS/ITFS licensees in or through whose licensed service area they intend to operate, and provide the technical parameters of the SDARS terrestrial repeater transmission facility.

C. *LPR interference to MDS/ITFS receivers.* To provide parity with the requirements imposed on WCS licensees to remedy blanketing interference caused to MDS/ITFS receivers (*See* 47 CFR 27.58), as proposed by several commenters in this proceeding, we seek comment on requiring SDARS licensees to remedy any blanketing interference caused to MDS/ITFS receivers from LPRs. We also seek comment on requiring the SDARS licensees to bear the full financial obligation to remedy interference from

their repeaters to MDS/ITFS block downconverters if all of the following conditions are met:

(1) The complaint is received by the SDARS licensee prior to February 20, 2002;

(2) The MDS/ITFS downconverter was installed prior to August 20, 1998;

(3) The SDARS terrestrial repeater station transmits at 50W or more peak EIRP; and

(4) The MDS/ITFS downconverter is located within a SDARS terrestrial repeater's free space power flux density contour of −34 dBW/m².

We also seek comment on the following concepts: that if the SDARS licensee cannot otherwise eliminate any interference that its repeater causes to MDS/ITFS reception, then that SDARS licensee must cease operations from the offending LPR facility. If SDARS licensees collocate their repeater antennas on the same tower, they shall assume shared responsibility for remedying interference complaints within the area determined by the −34 dBW/m² power flux density contour, unless the offending station can be readily determined and then that station operator shall assume full financial responsibility. If the complainant is also entitled to compensation from one or more licensees in the Wireless Communications Service pursuant to 47 CFR 27.58, we seek comment on whether the cost should be shared equally among all WCS and SDARS licensees that cause such interference.

IV. High Power Repeater (HPR) Operations

We seek comment on the following compensation methodology that will apply to SDARS licensees operating HPRs. This concept establishes a safe harbor in which SDARS licensees would not be required to coordinate with or compensate WCS licensees to resolve blanketing interference that may be caused to WCS receiving stations from SDARS repeaters. It also establishes ''zones'' outside of this safe harbor in which WCS licensees would be entitled to compensation to resolve interference from HPR operations. The methodology includes a schedule for providing compensation. We seek comment on this proposal and its implementation as well as any variations of this concept as set forth below. Specifically, we solicit comment on whether or not compensation should be provided for consumer premises equipment (CPE) and on whether or not there should be a limit of the SDARS licensees' financial liability.

A. *Permitted HPR Operations.* We seek comment on whether SDARS licensees should be permitted to operate HPRs at locations with technical parameters as limited by the Commission in the XM and Sirius STA Orders (*See* DA 01–2172 and DA 01–2171 (rel. September 17, 2001)) for 18 months after the effective date of the final rules and whether, within 15 days from the release date of these rules, the SDARS licensees should be required to file with the Commission technical information on HPRs that have been moved to an alternate location, reduced in power, or no longer in operation as a result of interference concerns with WCS, MDS or ITFS facilities prior to the release date of the final SDARS repeater rules.

B. *Safe Harbor.* We seek comment on whether SDARS licensees should have any obligation to coordinate with WCS stations, including WCS customer premises equipment, located within the power level contour that would be generated by a 2 kW EIRP LPR, and using free space loss and the specified receive system threshold characteristics of the affected WCS licensee, as follows:

Maximum LPR EIRP (kW)	LPR EIRP (dBm)	Maximum safe harbor distance from LPR to edge of contour (miles)			
		−25 dBm contour	−35 dBm contour	−45 dBm contour	−58 dBm contour
2	63	0.16	0.50	1.56	6.97

Free space path loss is defined as: $Loss_{dB}$ = 32.5 + 20log(distance in km) + 20log(frequency in MHz)

C. *Liability Zone.* We seek comment on whether SDARS licensees should be required to coordinate in good faith with WCS licensees with respect to WCS stations located outside of the Safe Harbor but located within the Liability Zone defined by the power level contour generated by the actual HPR EIRP, and using free space loss and the specified receive system threshold characteristics of the ''affected'' WCS licensee (*i.e.*, the affected licensee is that licensee with one or more stations inside the Liability Zone). At any stage in the 18-month period following the effective date of the SDARS repeater rules, an SDARS licensee may elect to reduce its HPR power level to any level that would reduce its Liability Zone. The edge of the Liability Zone shall not extend beyond the distances from the HPR according to the following:

HPR EIRP (kW)	HPR EIRP (dBm)	Maximum liability zone distance from HPR to edge of contour (miles)			
		25 dBm contour	−35 dBm contour	−45 dBm contour	−58 dBm contour
40	76	0.70	2.20	6.97	31.13

Free space path loss is defined as: $Loss_{dB}$ = 32.5 + 20log(distance in km) + 20log(frequency in MHz)

These tables are intended to provide generic rules that take into account the fact that the technical parameters of WCS systems may vary. The Safe Harbor and Liability Zone sizes depend upon the overload threshold of the affected WCS receiver. The tables provide the range of sensitivities of the WCS receivers to be deployed as stated in the record. For example, if the WCS licensee deploys receivers that overload at −25dBm, the first table indicates that the Safe Harbor maximum radius distance will be 0.16 miles. If the SDARS repeater operates at 40 kW with an omni-directional antenna, the second table indicates that the Liability Zone will have a maximum radius of 0.70 miles. If the SDARS licensee uses a 10 kW repeater, the Liability Zone radius would be calculated using the free space path loss formula to be 0.35 miles.

D. *Blanketing interference to WCS stations.* We seek comment on whether a WCS station located within the Liability Zone is considered to potentially receive blanketing interference from the notified HPR(s) and the affected WCS licensee is entitled to compensation according to the Compensation Schedule. Under this approach, SDARS and WCS licensees would be expected to coordinate in

good faith to avoid interference problems and to allow the greatest operational flexibility in each other's operations. To remedy actual blanketing interference to WCS stations already in operation or planned for operation in the 18-month period, either by compensation or power reductions, the licensees must, in as expeditious a manner as possible, exchange information about WCS station deployment (*e.g.*, the number of base stations planned to be in operation in the 18 months following the effective date of the SDARS rules; the station locations within the Liability Zone in order of anticipated deployment, if known; the technical characteristics of those stations; and the estimated reasonable cost to resolve interference to the WCS stations receiving blanketing interference from the specified HPR(s)).

E. *Compensation Schedule.* If an SDARS licensee is notified by an affected WCS licensee that it is receiving blanketing interference within the Liability Zone that prevents the provision of commercial service, the SDARS licensee shall immediately pay the reasonable costs of eliminating or mitigating such interference. This is similar to what the Commission has required of WCS licensees to do for MDS/ITFS licensees and of new FM broadcast licensees to do for complainants. (*See* 47 CFR 17.58, 73–318). The SDARS licensee shall compensate the WCS licensee for the cost of the components to protect its station receivers from blanketing interference caused by the HPRs (*e.g.*, filters for base stations or RF Automatic Gain Control for CPE). The following schedule sets forth the timeframes during which WCS licensees' interference complaints shall be remedied and the prorated financial liability of SDARS licensees following the effective date of the rules governing SDARS repeaters:

0 to 6 months—SDARS licensee pays 100% of components for base stations;

6 to 12 months—SDARS licensee pays 50% of components for base stations;

12 to 18 months—SDARS licensee pays 25% of components for base stations;

after 18 months—SDARS licensee has no financial liability.

Under this approach, for 18 months after the final rules are effective, the SDARS HPR operations would be limited to the locations and parameters identified in the STA requests. The population of HPRs would be frozen. After the 18 month period, any new HPR would have to be coordinated with affected WCS operations or would be limited in maximum power, as described below in section V., B. SDARS licensees would be obligated to abide by the final rules to ensure future protection to WCS licensees.

We seek comment on the appropriateness of including the cost of resolving interference to WCS CPE in the Compensation Schedule. We seek comment on the time within which SDARS licensees must mitigate interference to WCS CPE and whether or not we should require SDARS licensees to pay any compensation or provide compensation for up to 18 months for WCS CPE. We seek further comment on whether the SDARS licensees should be required to provide filters for WCS base stations or to pay all the costs associated with eliminating the interference for both base stations and CPE, including labor, as well as on any other aspects of possible interference mitigation. Moreover, we seek comment on whether the SDARS licensee's monetary liability to WCS licensees should be limited to a particular amount. If so, what is that amount and the rationale for it? We also generally seek comment on whether the resolution of interference should be left to the SDARS and WCS licensees.

F. *Blanketing interference to MDS/ITFS receivers.* Similar to the approach for SDARS licensees to remedy blanketing interference caused to MDS/ITFS receivers from LPRs until February 20, 2002 in Section III. C., we seek comment on applying this approach with regard to HPRs. Specifically, we seek comment on whether SDARS licensees should bear the full financial obligation to remedy interference to MDS/ITFS block downconverters if all of the following conditions are met:

(1) The complaint is received by the SDARS licensee prior to February 20, 2002;

(2) The MDS/ITFS downconverter was installed prior to August 20, 1998; and

(3) The MDS/ITFS downconverter is located within a SDARS HPR station's free space power flux density contour of -34 dBW/m^2.

We seek comment on requiring that if the SDARS licensee cannot otherwise eliminate interference caused to MDS/ITFS block downconverters, the SDARS licensee must reduce its power or cease operations from the offending SDARS HPR station. If SDARS licensees collocate their antennas on the same tower, they shall assume shared responsibility for remedying interference complaints within the area determined by the -34 dBW/m^2 power flux density contour, unless an offending station can be readily determined in which case the offending SDARS should be required to assume full financial responsibility. If the MDS/ITFS complainant is also entitled to compensation from one or more licensees in the Wireless Communications Service pursuant to § 27.58, the cost shall be shared equally among all WCS and SDARS licensees with stations causing such interference.

V. Operation of HPRs after the compensation schedule to WCS/MDS/ITFS licensees no longer applies

In addition to a methodology to limit interference and establish compensation to WCS and MDS/ITFS licensees, we seek comment on how to facilitate the future deployment of HPRs. We seek comment on whether to establish a power cap and a notification process for HPRs. We also request comment on a possible requirement that operator-to-operator agreements among SDARS and WCS/MDS/ITFS licensees be established before an SDARS licensee would be permitted to commence further HPR operations or other similar alternatives. Specifically, we seek comment on the following:

A. *MDS/ITFS Receivers.* We seek comment on imposing a requirement on SDARS licensees to provide notice to any MDS/ITFS licensee that may be operating in the vicinity of an HPR station: at least 90 days prior to commencing operations from any new HPR, the SDARS licensee shall notify all MDS/ITFS licensees, in or through whose licensed service area an SDARS licensee intends to operate, of the technical parameters of the SDARS terrestrial repeater transmission facility.

B. *WCS Stations.* We seek comment on how to regulate HPRs after the 18-month compensation period described previously has expired. One alternative would be to place a power cap on HPRs and establish a notification process for them similar to that proposed for MDS/ITFS receivers. Under this approach, all existing HPRs would be grandfathered and the power cap would apply to new repeaters after expiration of the compensation schedule in the approach described previously. Prior to commencing operation from any new HPR, the SDARS licensee would be required to provide a 90-day notice to WCS licensees. We specifically seek comment on what an appropriate power cap should be in the range of 2 kW to 40 kW. For example, is a 9 kW EIRP level (39.5 dBW, which is midway between the 2 kW (33 dBW) and 40 kW (46 dBW) powers established in the record as acceptable to WCS/MDS/ITFS licensees and desired by SDARS licensees, respectively) appropriate to apply to future HPRs? Would this power cap distribute equally among WCS and

SDARS licensees the responsibility to manage their operations in the presence of each other's service and provide for the ability of all services to deploy expeditiously? If applied to existing repeaters, what transition period would be necessary or appropriate?

Another alternative would be to permit HPR operations at power levels up to 40 kW EIRP only after prior agreement among SDARS and affected WCS licensees has been reached. In this case, each SDARS licensee would be required to exchange information with affected WCS licensees about its repeater deployment and technical parameters. The SDARS licensee would be required also to take all practical steps to locate additional HPRs in areas that will mitigate the potential for blanketing interference to WCS operations. Prior to commencing operation of an additional HPR, the SDARS licensee would be required to certify to the Commission that it has completed coordination of the HPR with all affected WCS licensees. We seek comment on these options and any other alternatives for the deployment of HPRs after the 18-month period has expired.

VI. Radio Frequency (RF) Safety

In February 1997, the Commission adopted rules for Wireless Communications Services. (*See* 62 FR 9636 (March 3, 1997)). In that Report and Order, the Commission modified § 1.1307(b) of its rules to require applicants proposing to operate fixed terrestrial stations in the 2305–2320 MHz and 2345–2360 MHz frequency bands to perform routine environmental evaluations if their station's EIRP exceeds 1640 Watts. *See* 47 CFR 1.1307(b), Table 1. We now seek comment on modifying this Section of the Commission's rules to accommodate SDARS repeaters governed by part 25, which will operate in the 2320–2345 MHz frequency bands. The proposal is based on suggestions offered by the DARS and WCS licensees. We seek comment on the proposed modification to Table 1 in § 1.1307 particularly from the standpoint of RF safety to the public. We specifically propose that actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared, are greater than 2000 W EIRP for satellite DARS terrestrial repeaters.

Procedural Matters: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments limited to the issues raised in this document no later than December 14, 2001 and reply comments no later than December 21, 2001. Because the DARS repeaters STAs expire on March 18, 2002 or on the implementation of permanent rules for repeater operations, whichever occurs first, we must adhere to the schedule set forth in this document and do not contemplate granting extensions of time. Comments should reference IB Docket No. 95–91 and should include the DA number on the front of this document, DA 01–2570. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). (*See* Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (May 1, 1998).) Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* In completing the transmittal screen, parties responding should include their full name, mailing address, and the applicable docket number, IB Docket No. 95–91. Parties filing comments on paper must file an original and four copies of each filing. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW, Room TW–A325, Washington, D.C. 20554. An additional copy of all pleadings should also be sent to Rockie Patterson, International Bureau, FCC Room 6–B524, 445 12th Street, SW, Washington, D.C. 20554. One copy of all comments should also be sent to the Commission's copy contractor, Qualex International, 445 12th Street, SW, Room CY–B402, Washington, D.C. 20554. Copies of all filings are available for public inspection and copying during regular business hours at the FCC's Reference Information Center, 445 12th Street, SW, telephone 202–857–3800; facsimile 202–857–3805.

For *ex parte* purposes, this proceeding continues to be a ''permit-but-disclose'' proceeding, in accordance with § 1.1200(a) of the Commission's rules, and is subject to the requirements set forth in § 1.1206(b) of the Commission's rules.

The Commission's Consumer Information Bureau Reference Information Center shall send a copy of this document, Including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

Initial Regulatory Flexibility Act Analysis

1. As required by the Regulatory Flexibility Act (RFA) (*see* 5 U.S.C. 603), the Bureau has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the International Bureau's document Requesting Further Comment on Selected Issues Regarding the Authorization of Satellite Digital Audio Radio Service Terrestrial Repeater Networks (SDARS document). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments on the document provided. The Bureau will send a copy of the SDARS document, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the SDARS document and IRFA (or summaries thereof) will be published in the **Federal Register**.

2. Need for and Objections of the Proposed Rules. This SDARS document seeks comments on specific proposals to resolve issues regarding the proposed use of satellite digital audio radio service (SDARS) terrestrial repeaters in conjunction with SDARS systems.

The Bureau intends to evaluate whether the proposed rules will facilitate the efficient implementation of SDARS while seeking to limit or mitigate interference to terrestrial operators. The proposals define a compensation methodology for SDARS licensees to pay for the components necessary for WCS licensees to eliminate the effects of blanketing interference to WCS receivers. It also seeks comment on provisions that would resolve potential interference to MDS and ITFS licensees.

3. Legal Basis. This SDARS document is adopted pursuant to sections 1, 4(i), 4(j), 303(c), 303(f), and 303(g) of the Communications Act of 1934, as amended, 47 U.S.C. 151(i), 154(i), 154(j), 303(c), 303(f) and 303(g).

4. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' or ''small concern'' under Section 3 of the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of

1992, there were approximately 275,801 small organizations. ''Small governmental jurisdiction'' generally means ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000. As of 1992, there were approximately 85,006 governmental entities in the United States. This number includes 38,978 counties, cities, and towns; of these 37,566, or 96%, have populations of fewer than 50,000. The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (96%) are small entities.

SDARS. The Commission has not developed a definition of small entities applicable to geostationary or non-geostationary orbit broadcast satellite operators. Therefore, the applicable definition of small entity is the definition under Small Business Administration (SBA) rules applicable to the Communications Services, Not Elsewhere classified. This definition provides that a small entity is one with $11.0 million or less in annual receipts. There are only two SDARS providers authorized to provide service in the DARS spectrum band, XM Radio, Inc. and Sirius Satellite Radio, Inc. While neither has implemented nationwide service, both entities have financing of over $100 million. In addition, the DARS licensees have significant partnership interests with large corporations: General Motors in XM Radio, Inc. and DiamlerChrysler in Sirius Satellite Radio. Because of the above and the high implementation and operating costs for SDARS systems, we do not believe either DARS licensee qualifies as a small entity.

Wireless Communications Services (WCS). This service can be used for fixed, mobile, radiolocation and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions. The FCC auctioned geographic area licenses in the WCS service. In the auction, there were seven winning bidders that qualified as very small business entities, and one that qualified as a small business entity. We conclude that the number of geographic area WCS licensees affected includes these eight entities.

Multipoint Distribution Service (MDS). The Commission refined the definition of ''small entity'' for the auction of MDS as an entity that together with its affiliates has average gross annual revenues that are not more than $40 million for the preceding three calendar years. This definition of a small entity is described in the Commission's Report and Order concerning MDS auctions, and has been approved by the SBA. The Commission completed its MDS auction in March 1996 for authorizations in 493 basic trading areas (BTA's). Of 67 winning bidders, 61 qualified as small entities. Five bidders indicated that they were minority owned and four winners indicated that they were women owned businesses. MDS is an especially competitive service, with approximately 1,573 previously authorized and proposed MDS facilities. Information available to us indicates that no MDS facility generates revenue in excess of $11 million annually. We tentatively conclude that for purposes of IRFA, there are 1,634 small MDS providers as defined by the SBA and the Commission's auction rules.

Instructional Television Fixed Service (ITFS). There are presently 2,032 ITFS licensees. All but one hundred of these licenses are held by educational institutions. Educational institutions are included in the definition of a small business. We do not, however, collect annual revenue data for ITFS licensees and are not able to ascertain how many of the 100 non-educational licensees would be categorized as small under the SBA definition. Thus, we tentatively conclude that at least 1,932 ITFS licensees are small businesses.

5. Description of Projected Reporting, Record keeping and Other Compliance Requirements. Under the proposals licensees, such as WCS, MDS and ITFS, potentially affected by the operation of SDARS repeaters will have to undertake a minimal engineering analysis to determine whether it has operations within the liability zone or the safe harbor as defined in the SDARS document. This analysis can be completed using the technical information provided by the DARS licensees and basic commercially available software. Thus, there may be minimal costs to these licensees associated with conducting the engineering study. As noted, resolution of any actual interference would be at the expense of the DARS licensee provided the WCS, MDS or ITFS licensees are in the established vicinities and file timely complaints as set forth in the SDARS document.

Compliance requirements for the DARS licensees, if it is determined that there is actual interference, include contacting the affected licensee and remedying the interference. The remedy may involve weighing options such as reducing the repeater's power or compensating the affected licensees by providing equipment and labor to alter the affected licensee's receivers. Costs to the DARS licensees may relate to engineering studies, cost analyses and expenses in equipment and labor. These costs may be determined on a case-by-case basis.

6. Steps Taken to Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) use of performance, rather than design standards; and (4) and exemption from coverage of the rule, or any part there of, for small entities.

The proposed rule represents an alternative to extremes presented by the licensees involved in this proceeding and spreads the economic impact and business decisions to resolve interference among the licensees. Our proposed alternatives are based on the actual performance of equipment deployed and would benefit small entities affected by interference from the SDARS use of their terrestrial repeaters by providing assurances that interference to their operations will be resolved by the DARS licensees within the parameters set forth in the SDARS document. In addition, we have sought comment on whether the proposed compensation schedule and associated time frames are sufficient, and especially seek comment from small entities, given that they may be some of the potentially affected licensees.

7. Federal Rules that duplicate, Overlap or Conflict with the Commission's Proposals. None.

List of Subjects

47 CFR Part 1

Environmental impact statements, Satellites.

Federal Communications Commission.

Jennifer Gilsenan,

Branch Chief, Satellite Policy Branch, International Bureau.

Proposed Rule

For the reasons stated in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

1. The authority citation for part 1 continues to read as follows:

Authority: 47 U.S.C. 151, 154(I), 154(j), 155, 225, 303(r), 309 and 325(e).

2. Section 1.1307 is amended by revising the entry for Satellite Communications in Table 1 to read as follows:

§ 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

* * * * *

TABLE 1—TRANSMITTERS, FACILITIES, AND OPERATIONS SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

Service (title 47 CFR rule part)	Evaluation required if
* * * * *	
Satellite Communications (part 25)	Satellite DARS Terrestrial Repeaters: >2000 W EIRP All others included.
* * * * *	

* * * * *

[FR Doc. 01–29328 Filed 11–21–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 68

[WT Docket No. 01–309; FCC 01–320]

Hearing Aid Compatibility with Public Mobile Service Phones

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document initiates a proceeding in which the Commission considers whether to continue or eliminate the exemption of public mobile service phones from legislatively mandated hearing aid compatibility requirements.

DATES: Submit comments on or before January 11, 2002, and submit reply comments on or before February 11, 2002. Written comments on the proposed information collections are due January 22, 2002. Written comments on the proposed information collections must be submitted by the Office Management and Budget (OMB) on the proposed information collections on or before March 25, 2002.

ADDRESSES: Send comments and reply comments to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *jboley@fcc.gov,* and to Ed Springer, OMB Desk Officer, 10236 NEOB, 725–17th Street, NW., Washington, DC 20503 or via the Internet to *Edward.Springer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Mindy Littell, 202–418–1310 (voice) or (202) 418–1169 (TTY); or Dana Jackson, Consumer Information Bureau, Disabilities Rights Office, (202) 418–2517 (voice) or 418–7898 (TTY). For additional information concerning the information collections contained in this document, contact Judy Boley at 202–418–0214, or via the Internet at *jboley@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making (NPRM) in WT Docket No. 01–309, FCC 01–320, adopted October 29, 2001, and released November 14, 2001. The complete text of the NPRM and Initial Regulatory Flexibility Analysis is available on the Commission's Internet site, at www.fcc.gov. It is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC, and may be purchased from the Commission's copy contractor, Qualex International, CY–B402, 445 12th Street, SW., Washington, DC. Comments may be sent as an electronic file via the Internet to http://www.fcc.gov/e-file/ecfs.html, or by e-mail to *ecfs@fcc.gov.*

Synopsis of the NPRM

1. In this NPRM, the Commission reexamines the exemption, adopted pursuant to the direction of the Hearing Aid Compatibility Act of 1998 (HAC Act), of public mobile service phones from the hearing aid compatibility requirements of that Act. This NPRM is adopted pursuant to the Commission's obligation under the HAC Act to assess periodically whether the exemptions from the hearing aid compatibility requirement continue to be warranted. Currently, many people who use hearing aids or who have cochlear implants have difficulty finding a digital wireless mobile telephone that functions effectively with those devices because of interference and compatibility problems. A Public Notice was issued in October 2000 seeking comment on a request from the Wireless Access Coalition that the Commission reopen the petition for rulemaking filed in 1995 on behalf of the HEAR–IT NOW Coalition, seeking to revoke the exemption for Person Communications Services (PCS) from the Commission's hearing aid compatibility requirements. The NPRM seeks comment to expand the record thus far in order to establish a reliable, extensive record on which to base its decision to continue, limit, or eliminate the PCS exemption.

2. The HAC Act, as indicated in paragraphs 16 through 18 of the NPRM, mandates that once technical standards for hearing aid compatibility are established, covered telephones must provide internal means for effective use with hearing that are designed to be compatible with telephones that meet such technical standards. (47 U.S.C. 610(b)(1). This portion of the statute appears to require, first, the establishment of technical standards governing wireless hearing aid compatibility. Therefore, the Commission tentatively concludes that, if it removes or limits the exemption for public mobile services, the industry will be required to develop technical standards for compatibility between covered wireless devices and hearing

aids. The Commission invites comment on this tentative conclusion.

3. The statute also requires that once these standards are established, the wireless industry will be responsible for providing *internal means* for making the covered telephones compatible with hearing aids. The Commission seeks comment on possible interpretations of ''internal means.''

4. Third, the HAC Act appears to limit the compatibility requirement to only ''hearing aids that are designed to be compatible with telephones that meet established technical standards for hearing aid compatibility.'' The Commission seeks comment on its assumption that this means that there may be some instances in which a hearing aid is not designed to be compatible with wireless telephones.

5. The Commission also seeks comment on the four criteria specified by the HAC Act which, if satisfied, would compel the Commission to ''revoke or otherwise limit'' the exemptions. Thus, the Commission seeks comment on whether these criteria are satisfied and on other more specific issues in this regard, as detailed in paragraphs 20 through 29 of the NPRM. These four criteria are: (1) Whether revoking or limiting the exemptions is in the public interest; (2) whether the continuation of the exemptions without revocation or limitation would have an adverse effect on people with hearing disabilities; (3) whether compliance with the requirements of the hearing aid compatibility rule is technologically feasible for the telephones to which the exemption applies; and (4) whether compliance with the requirements of the rule would not increase costs to such an extent that the telephones to which the exemption applies could not be successfully marketed.

6. Paragraphs 30 and 31 of the NPRM seek comment on the proper scope of the exemptions and on possible ways the Commission could limit the exemptions. Included in the discussion of implementation issues in paragraphs 32 through 35 of the NPRM, the Commission solicits comment on the possibility of a phased-in approach to implementation if the exemption is ultimately limited or revoked. Additionally, the Commission invites comment on ways in which it can stay informed on progress toward compliance by both the wireless industry and the hearing aid manufacturing industry. In this regard, the Commission suggests a quarterly report to help it monitor activities of the involved industries. Also, the Commission seeks comment on possible complaint procedures if the exemption is either limited or revoked.

Initial Regulatory Flexibility Analysis

7. This is a summary of Initial Regulatory Flexibility Act Analysis (IRFA) for the NPRM. The full text of the IRFA may be found in Appendix B of the NPRM.

8. As required by the Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 603, the Commission has prepared an IRFA of the possible significant economic impact on small entities of the policies and rules proposed in the NPRM. The Commission requests written public comment on the analysis. In order to fulfill the mandate of the Contract with America Advancement Act of 1996 regarding the Initial Regulatory Flexibility Analysis, the Commission asks a number of questions in the IRFA regarding the prevalence of small businesses in the affected industries.

Initial Regulatory Flexibility Analysis

9. As required by Section 603 of the Regulatory Flexibility Act (RFA), the Commission has prepared this IRFA of the possible significant economic impact on small entities by the policies and rules proposed in this Notice of Proposed Rule Making NPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to this IRFA and must be filed by the deadlines for comments on the NPRM provided in paragraph 38 of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

A. Need for, and Objectives of, the Proposed Rules

10. The Commission adopts the NPRM in order to examine the continued appropriateness of the exemption from the requirements of the Hearing Aid Compatibility Act (HAC Act) provided to public mobile services. The HAC Act mandates a periodic review of the exemption, and the Commission believes a proceeding should be initiated to consider whether it is appropriate to revoke or limit the exemption with respect to telephones used with public mobile services. This decision would be based on the four criteria established by the HAC Act that, if satisfied, would compel the Commission to revoke or otherwise limit the exemptions.

B. Legal Basis

11. The proposed action is authorized under the Communications Act of 1934 as amended, sections 4(i), 303(r) and 710(a) and (b), 47 U.S.C. 154(i), 303(r) and 610(a) and (b).

C. Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply

12. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

13. Neither the Commission nor the SBA has developed definitions for small providers of the specific industries affected. Therefore, throughout our analysis, unless otherwise indicated, the Commission uses the closest applicable definition under the SBA rules, the North American Industry Classification System (NAICS) standards for ''Cellular and Other Wireless Telecommunications'' and ''Wired Telecommunications Carriers.'' According to this standard, a small entity is one with no more than 1,500 employees. To determine which of the affected entities in the affected services fit into the SBA definition of small business, the Commission has consistently referred to Table 5.3 in *Trends in Telephone Service* (*Trends*), a report published annually by the Commission's Common Carrier Bureau.

14. Wireless Telephones Including Cellular, Personal Communications Service (PCS) and SMR Telephony Carriers. There are 806 entities in this category as estimated in *Trends,* and 323 such licensees in combination with their affiliates have 1,500 or fewer employees and thus qualify using the NAICS guide, as small businesses.

15. Other Mobile Service Providers. *Trends* estimates that there are 44 providers of other mobile services, and again using the NAICS standard, 43 providers of other mobile services utilize with their affiliates 1,500 or fewer employees and thus may be considered small entities.

16. Hearing Aid Equipment Manufacturers. Hearing aid manufacturers are not regulated by the Commission, but may be affected by the proposed actions taken in this proceeding. In light of the potential

impact, we have chosen to include hearing aid manufacturers in this IRFA, although we are not required to do so. Hearing aid manufacturers are not licensed, but the Commission estimates that there are approximately 35 to 40 hearing aid manufacturers.

17. Handset Manufacturers. The Commission does not license or regulate handset manufacturers. Therefore, no data exists indicating the number of entities manufacturing handsets. The applicable definition of small entity in this respect is the definition under the SBA rules applicable to Communications Services, Not Elsewhere Classified. This definition provides that a small entity is one with $11 million or less in annual receipts. According to Census Bureau data, there are 848 firms that fall under the category of Communications Services, Not Elsewhere Classified. Of those approximately 775 reported annual receipts of $11 million or less and qualify as small entities. Thus, the Commission, for purposes of this analysis estimates that no more than 775 handset manufacturers qualify as small entities.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

18. In the event that the HAC Act exemption is revoked, telephones used with public mobile services will be required to be compatible with hearing aids and cochlear implants. While it is possible that, in this proceeding, the scope of the exemption may be fashioned so that not all telephones used with public mobile services will be subject to the hearing aid compatibility requirements, for purposes of this analysis we will assume the broadest possible impact. The NPRM first seeks comment on ways in which the Commission can stay informed on progress toward compliance by both the wireless industry and the hearing aid manufacturing industry, such as through a quarterly reporting requirement. Also, the NPRM tentatively concludes that, in the event the Commission removes or limits the exemption for public mobile services, the industry will be required to develop technical standards for compatibility between covered wireless devices and hearing aids. One implementation approach proposed by the Cellular Telecommunications & Industry Association, provides that wireless devices would be categorized and ''paired'' with a categorized hearing aid to enable the use of the two devices together. In the event that the Commission decides to limit or revoke the exemption, and it determines that the CTIA plan is the appropriate mechanism to satisfy the requirements of the HAC Act, the NPRM seeks comment on the series of steps CTIA asserts will be necessary before such a pairing approach can be implemented, part of which necessitates an educational effort to inform consumers and retail sales personnel about the plan. Finally, if the exemption is either removed or limited, complaint procedures would be adopted and the affected licensees would need to participate in the complaint process.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

19. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

20. The NPRM seeks comment on a number of matters related to implementation of hearing aid compatibility in the wireless devices used with public mobile services, all of which could affect small entities. We note that, to the extent that manufacturers would make changes to telephone handsets to enable carriers subject to the hearing aid compatibility requirements to comply with those requirements, in many cases, those updated handsets may be usable by smaller carriers as well as larger carriers. The two most obvious alternatives in this proceeding are whether to keep the exemption or whether to eliminate or limit the exemption. Depending on the final action taken, small entities could be affected. The NPRM seeks comment on the best way to implement the hearing aid compatibility requirements, and indicates that a phased-in approach might be a good way to minimize burdens on all carriers, including small entities. Because of the impact of the rule on people with hearing disabilities, the Commission has little flexibility in terms of providing a less burdensome approach for small entities. The incompatibility between hearing aids and wireless devices affects all persons with hearing disabilities in the same way regardless of the size of the carrier or manufacturer. In paragraph 26, the NPRM seeks comment on whether the ''pairing'' approach suggested by CTIA, along with its educational component, would be a satisfactory solution to the incompatibility problem. The NPRM, in paragraph 31, also asks whether the exemptions should be limited with respect to fewer than all telephones used with public mobile services. The Commission invites comment on the impact on small entities of the alternatives here suggested. The Commission further invites interested parties to offer additional alternatives.

21. In paragraph 32, the NPRM seeks comment on whether a reporting requirement is needed to assist the Commission in monitoring the industry's progress toward implementation of hearing aid compatibility in the covered wireless devices. Commenters are encouraged to provide input on the content and frequency of these reports so as to facilitate monitoring and the exchange of information between the wireless industry and the hearing aid manufacturing industry. Because of the compelling public interest in making public service telephones accessible to persons with hearing disabilities, the Commission proposes to require quarterly reports by affected entities to ensure that progress is being made toward achieving hearing aid compatibility. Paragraphs 28 and 29 of the NPRM seek comment on how to minimize the financial burden on those currently exempt from hearing aid compatibility if the exemptions are limited or removed.

F. Federal Rules That May Overlap, Duplicate, or Conflict With the Proposed Rules

22. None.

Ex Parte Presentations

23. For purposes of this permit-but-disclose notice and comment rulemaking proceeding, members of the public are advised that *ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed under the Commission's Rules. (*See generally* 47 CFR 1.1202, 1.1203, 1.1206((a).)

Pleading Dates

24. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, interested parties may file comments on or before January 11, 2002, and reply comments on or before February 11, 2002. All relevant and timely comments will be

considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, interested parties must file an original and four copies of all comments, reply comments, and supporting comments. If interested parties want each Commissioner to receive a personal copy of their comments, they must file an original plus nine copies. Interested parties should send comments and reply comments to the Office of the Secretary, Federal Communications Commission, Room TW–A325, 445 Twelfth Street, SW., Washington, DC 20554, with a copy to Mindy Littell, Policy Division, Wireless Telecommunications Bureau, 445 Twelfth Street, SW., Washington, DC 20554.

25. Comments may also be filed using the Commission's Electronic Comment Filing System (ECFS). Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet E-Mail. To obtain filing instructions for E-Mail comments, commenters should send an e-mail to *ecfs@fcc.gov*, and should include the following words in the body of the message, ''get form <your E-Mail address>.'' A sample form and directions will be sent in reply.

26. Comments and reply comments will be available for public inspection during regular business hours at the FCC Reference Center, Room CY–A257, at the Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. Copies of comments and reply comments are available through the Commission's duplicating contractor: Qualex International, CY–B402, 445 12th Street, SW., Washington, DC 20054, (202) 863–2893, e-mail *QUALEXINT@AOL.COM.*

Ordering Clauses

27. Authority for the issuance of this Notice of Proposed Rule Making is contained in sections 4(i), 303(r) and 710(a) and (b) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r) and 610(a) and (b).

28. The Commission's Consumer Information Bureau, Reference Information Center, shall send a copy of this Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Paperwork Reduction Analysis

33. This NPRM contains proposed information collections. As part of our continuing effort to reduce paperwork burdens, the Commission invites the general public and the Office of Management and Budget (OMB) to take this opportunity to comment on the information collections contained in this NPRM, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due January 22, 2002. OMB comments are due March 25, 2002. Comments should address: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (2) the accuracy of the Commission's burden estimates; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

OMB Approval Number: 3060–XXXX.

Title: Exemption of Public Mobile Service Phone from the Hearing Aid Compatibility Act: Notice of Proposed Rulemaking (NPRM).

Form No.: N.A.

Type of Review: New collection.

Respondents: Individuals or households; business or other for profit.

Number of Respondents: 965 respondents; 3,860 responses.

Estimated Time Per Response: 2 to 8 hours.

Frequency of Response: On occasion and quarterly reporting requirement and third party disclosure requirement.

Total Annual Burden: 20,265 hours.

Total Annual Cost Burden: N/A.

Needs and Uses: The reporting requirement, if adopted, will be used by the Commission to monitor wireless carriers and handset and hearing aid manufacturers progress towards compliance with hearing aid compatibility requirements, if the current exemption is limited or revoked. Technical standards are mandated by the Hearing Aid Compatibility Act of 1988, if the Commission decides to limit or revoke the current exemption, and will be used as a guide to compliance with hearing aid compatibility requirements.

List of Subjects in 47 CFR Part 68

Communications common carriers, Communications equipment.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 01–29293 Filed 11–21–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AF45

Endangered and Threatened Wildlife and Plants; Reopening of Comment Period on the Proposed Rule To List the Southwestern Washington/Columbia River Coastal Cutthroat Trout in Washington and Oregon as Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service) are reopening the comment period on the proposed rule to list the Southwestern Washington/Columbia River coastal cutthroat trout Distinct Population Segment (DPS) in Washington and Oregon to collect new information that may be available concerning coastal cutthroat trout in the proposed area.

DATES: We will accept public comments until December 24, 2001.

ADDRESSES: Comments and materials concerning this notice should be sent to U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, Oregon 97266, or email: coastal__cutthroat@fws.gov. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Kemper McMaster, State Supervisor at the above address, or telephone 503/231–6179; facsimile 503/231–6195

SUPPLEMENTARY INFORMATION

Background

On April 5, 1999, the National Marine Fisheries Service (NMFS) and the Service published a notice in the **Federal Register** (64 FR 16397) proposing to list the coastal cutthroat trout (*Oncorhynchus clarki clarki*) population in southwestern Washington and the Columbia River, excluding the Willamette River above Willamette Falls, as threatened pursuant to the Endangered Species Act of 1973, as

amended (Act). On November 22, 1999, the Service assumed all Act regulatory jurisdiction over coastal cutthroat (65 FR 21376). The change in jurisdiction resulted from a joint agency determination that coastal cutthroat trout spend the majority of their life cycle in fresh water habitat. The Service published a notice in the **Federal Register** (65 FR 20123) on April 14, 2000, to extend the deadline from April 5, 2000, to October 5, 2000 for the final action on the proposed rule to list this population in Washington and Oregon, and to provide a 30-day comment period. The 6-month extension was necessary to obtain and review new information regarding the status of this population. On July 14, 2000, the Service published a notice in the **Federal Register** (65 FR 43730) to clarify the take prohibitions for coastal cutthroat trout and provided for a 30-day public comment period. This notice was necessary to answer questions we had received regarding the application of the take prohibitions of section 9 of the Act to the potential listing of the coastal cutthroat trout as threatened. In October, 2000, the Service suspended work on the proposed listing of the coastal cutthroat trout due to budgetary limitations. On August 29, 2001, the Service issued a press release announcing that, as part of a settlement agreement with conservation groups, we will re-commence work on the final listing decision for the Southwestern Washington/Columbia River coastal cutthroat trout DPS.

In association with work on the listing decision, the Service has also engaged the Oregon and Washington Departments of Fish and Wildlife in discussions of how recreational fishing activities in those states influence the status of the species, and whether application of take prohibitions with respect to these activities would be necessary or advisable should the species be listed. If the Service determines that such application would not be necessary or advisable for the conservation of coastal cutthroat trout, it will propose related special rules under section 4(d) of the Act in future publications of the **Federal Register**.

At this time, the Service is seeking any new information on the coastal cutthroat trout population in southwestern Washington and the Columbia River. We are interested in comments and information regarding: (1) Biological or other relevant data concerning any threat to coastal cutthroat trout; (2) The range, distribution, population size, and demographics of coastal cutthroat trout in southwestern Washington and the Columbia River, including information on resident coastal cutthroat trout above barriers; (3) Current or planned activities in the subject area and their possible impacts on the species; (4) Potential effects of forest and agricultural practices, hatchery production, and other human induced impacts; (5) The contribution of resident, above-, and below-barrier coastal cutthroat trout sub-populations to the anadromous life history component; and (6) Efforts being made to protect native, naturally reproducing populations of Southwestern Washington/Columbia River coastal cutthroat trout. The comment period closes December 24, 2001. Comments should be submitted to the Service office listed in the **ADDRESSES** section.

Author

The primary author of this notice is Robin Bown, U.S. Fish and Wildlife Service (see **ADDRESSES** section).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 8, 2001.

Acting Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

[FR Doc. 01–29218 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AH79

Migratory Bird Hunting; Proposal for Migratory Game Bird Hunting Regulations; Withdrawal

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: The U.S. Fish and Wildlife Service (hereinafter Service or we) proposed in an earlier **Federal Register** notice to change certain parts of the regulatory alternatives for the 2001–02 duck hunting seasons for States in the Lower Region (Arkansas, Louisiana, Kentucky, Alabama, Mississippi and Tennessee) of the Mississippi Flyway. Based on a review of public comment and other considerations, the Service is withdrawing the proposal of October 11, 2001, and discusses possible ways to address the issue of framework opening and closing dates in the future.

ADDRESSES: You may inspect comments during normal business hours in room 634, Arlington Square Building, 4401 N. Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Jonathan Andrew, Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, (703) 358–1714.

SUPPLEMENTARY INFORMATION: On October 11, 2001, we published in the **Federal Register** (66 FR 51919) a proposed rule that would change the regulatory alternatives for the 2001–02 duck hunting seasons for States in the Lower Region (Arkansas, Louisiana, Kentucky, Alabama, Mississippi and Tennessee) of the Mississippi Flyway to allow for a season length of 60 days beginning no earlier than September 29 and ending no later than January 31. The comment period closed on October 26, 2001.

Review of Public Comments

Written comments from the National Flyway Council, the Atlantic Flyway Council and five Atlantic Flyway States (GA, FL, NJ, SC, VT), the Mississippi Flyway Council's Upper Region Regulation Committee and eight Mississippi Flyway States (IL, IN, IA, KY, MI, MN, MO, WI), the Central Flyway Council and two Central Flyway States (SD, TX), and the Pacific Flyway Council and three Pacific Flyway States (AZ, CA, WY) all strongly opposed the proposed rule, questioning the biological foundation for the proposal and stating that it circumvents the Flyway Council process, among other concerns. A written comment from Senator Paul Wellstone and Senator Mark Dayton strongly opposed the proposal. Written comments from the International Association of Fish and Wildlife Agencies, Louisiana Wildlife Federation, Mississippi Wildlife Federation, Boone & Crockett Club, The Wildlife Society, Dallas Safari Club, Wildlife Forever, Texas Wildlife Association, Max McGraw Wildlife Foundation, Indiana Grand Kankakee Marsh Restoration project, and the Izaak Walton League of America all opposed the proposal, calling it arbitrary and capricious and questioning whether it violated Administrative Procedures Act. Written comments from 12 private individuals opposed the proposal. Electronic comments opposing the proposal were received from 231 individuals.

Comments favoring the proposal included written comments from the State of Alabama and 5 individuals, and electronic comments from 27 individuals.

Service Response

The U.S. Fish and Wildlife Service regulates the earliest and latest dates

that States can select for duck-hunting seasons within alternative regulatory frameworks. The effects of extending these dates have been the subject of recent debate within the waterfowl management community, and this issue remains unresolved. On October 11, 2001, we proposed, upon reconsideration of the previously-established ''liberal'' alternative for the Lower Region (Alabama, Arkansas, Louisiana, Kentucky, Mississippi, and Tennessee) of the Mississippi Flyway, a framework opening date of no earlier than September 29 and a closing date of no later than January 31, with no reduction (offset) in season length. As indicated above, the vast majority of the comments received during the public comment period were strongly opposed to the proposal, asserting that the proposal: (1) Disregards the integrity of the cooperative process to develop hunting regulations that has been successfully in place for many years; (2) fails to consider biological, technical, and social impacts; (3) established a dangerous precedent in the regulations process; (4) neglects potential impacts on other species besides the mallard; (5) exacerbates an already unequal distribution of harvest and hunter opportunity; (6) disregards implications to other states; (7) erodes the long-established Flyway Council system; and (8) ignores efforts of the Flyway Councils, National Flyway Council, and the U.S. Fish and Wildlife Service to reach consensus on resolving this issue. As a result of these comments and concerns, the Service is withdrawing the proposal of October 11, 2001, and will maintain the regulatory alternatives for the 2001–02 duck hunting seasons that were finalized on September 27, 2001 (**Federal Register,** 66 FR 32297). The Service intends to use elements of the National Flyway Council's recommendation in its proposed rules for the 2002–2003 hunting season.

As part of continuing efforts to develop a resolution to the framework-date issue, the Service plans to meet in early December with a newly-formed working group established by the International Association of Fish and Wildlife Agencies, representing a cross-section of all Flyway Councils and States, in order to develop a proposal for framework opening and closing dates for the 2002–2003 duck hunting season. The encompassing objective of this effort will be to place the resolution of this issue back into the cooperative process between the States and the Federal Government for developing annual migratory game bird hunting regulations.

At this meeting, the Service will propose that the group consider revising the current regulatory packages and extending the opening and closing dates for the 2002–03 duck hunting season. As the basis for this proposal, key elements of the National Flyway Council recommendation for the 2001–2002 season will be used; that is, a framework opening date of the Saturday nearest September 24 and a closing date of the last Sunday in January, with no offsets in days or bag limits, in the ''moderate'' and ''liberal'' regulatory packages. In order to resolve a number of critical technical and administrative issues, the Service will propose that any changes to existing framework be achieved within the context of adaptive harvest management. This approach, building on the longstanding consensus of states, Flyway Councils, and the Service to pursue an adaptive approach to managing waterfowl harvests, would be designed to help identify the effects of changes in framework dates, while ensuring that we can account for uncertainty surrounding harvest and population impacts in each regulatory decision. In the coming months, the Service and State technical representatives will consider various alternative hypotheses that specify possible expected changes in mallard harvests associated with widespread application of extended framework dates and explore their management implications. Any proposed changes in framework dates would be developed with the tacit understanding that the Flyway Councils are prepared to accept the changes in harvest distribution that might occur. Also, there is the potential for adverse biological impacts to species other than mallards, such as wood ducks, and especially those species currently below objective levels (e.g. pintails, scaup), therefore, any changes to framework dates will require close inspection of relevant harvest and population data.

Successful implementation of changes to framework dates for the 2002–03 hunting season will require additional funding to support the maintenance of a reliable monitoring program for North American waterfowl, including the initiation of a band reporting rate study in 2002 that will allow the estimation of realized harvest rates for mallards and other important waterfowl species, continued efforts to improve the national harvest survey, and enhancements to aircraft survey capabilities.

Following the outcome of the December meeting with the Flyway Councils and states, the Service will begin to prepare its first **Federal Register** document for the 2002–03 regulations-development cycle (Preliminary Rule, to be published in March 2002, prior to the Flyway Council meetings), in which it will announce its intent to propose changes to framework dates. This document will also include additional information regarding progress in addressing monitoring and evaluation concerns expressed earlier and provide specific alternatives to revise the administrative and procedural process for regulations development.

Dated: November 16, 2001.

Joseph E. Doddridge,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–29235 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–55–M

Notices

Federal Register
Vol. 66, No. 226
Friday, November 23, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. ST–01–04]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved information collection for Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides (7 CFR part 110).

DATES: Comments on this notice must be received by January 22, 2002.

ADDITIONAL INFORMATION OR COMMENTS: Contact Bonnie Poli, Chief, Pesticide Records Branch, Science and Technology, AMS, 8609 Sudley Road, Suite 203, Manassas, VA 20110–4582, Telephone (703) 330–7826, Fax (703) 330–6110.

SUPPLEMENTARY INFORMATION:

Title: Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides.

OMB Number: 0581–0164.

Expiration Date of Approval: June 30, 2002.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The regulations, ''Recordkeeping Requirements for Certified Applicators of Federally Restricted Use Pesticides'' require certified pesticide applicators to maintain records of federally restricted use pesticide applications for a period of two years. The regulations also provide for access to pesticide records or record information by Federal or State officials, or by licensed health care professionals when needed to treat an individual who may have been exposed to restricted use pesticides, and penalties for enforcement of the recordkeeping and access provisions.

The Food, Agriculture, Conservation, and Trade Act of 1990, (Pub. L. 101–624; 7 U.S.C. 136i–1), referred to as the FACT Act, directs and authorizes the Department to develop regulations which establish requirements for recordkeeping by all certified applicators of federally restricted use pesticides. A certified applicator is an individual who is certified by the Environmental Protection Agency (EPA) or a State under cooperative agreement with EPA to use or supervise the use of restricted use pesticides.

Section 1491 of the FACT Act directs and authorizes the Department of Agriculture to ensure compliance with regulations as the Department may prescribe, including levying penalties, for failure to comply with such regulations.

Because this is a regulatory program with enforcement responsibility, USDA must ensure that certified applicators are maintaining restricted use pesticide application records for the two year period required by the FACT Act. To accomplish this, USDA must collect information through personal inspections of certified applicator's restricted use pesticide application records.

The information collected is used only by authorized representatives of the USDA (AMS, Science and Technology national staff, other designated Federal employees, and designated State supervisors and their staffs), which are designated access to the record information through section 1491, subsection (b) of the FACT Act. The information is used to administer the Federal Pesticide Recordkeeping Program. The Agency is the primary user of the information, and the secondary user is each designated State agency which has a cooperative agreement with AMS.

Estimate of Burden: Public reporting burden for this collection of information is estimated as follows:

(a) Approximately 602,661 certified private applicators (recordkeepers) apply restricted use pesticides. It is estimated that on average certified private applicators have a total annual burden of .415 hours per recordkeeper. Of the 602,661 certified private applicators, approximately 4,600 are selected annually for recordkeeping inspections. It is estimated that a private applicator that is subject to a pesticide record inspection has an annual burden of .85 hours, which contributes to a total annual burden of 3910 hours.

(b) There are approximately 308,443 certified commercial applicators nationally who are required to provide copies of restricted use pesticide application records to their clients. It is estimated that certified commercial applicators have a total annual burden of 1,520,007 hours.

(c) It is estimated that State agency personnel who work through cooperative agreements with AMS to inspect certified private applicator's records have a total annual burden of 11,020 hours.

Respondents: Certified private and commercial applicators, State governments or employees, and Federal agencies or employees.

Estimated Number of Respondents: 915,780—The total number of respondents includes approximately 308,443 certified commercial applicators, 602,661 certified private applicators (recordkeepers) and designated State agency personnel utilized to inspect certified private applicator's records.

Estimated Number of Responses per Respondent: The estimated number of responses per respondent is as follows:

(a) It is estimated that certified private applicators (recordkeepers), record on an average 5 restricted use pesticide application records annually.

(b) It is estimated that certified commercial applicators provide 616 copies of restricted use pesticide records to their clients annually.

(c) State agency personnel, who work under cooperative agreements with AMS to conduct restricted use pesticide records inspections, have approximately 5,700 responses annually.

Estimated Total Annual Burden on Respondents: 1,785,041; This revision in the Total Annual Burden on Respondents decreases the current burden by 43,411 hours.

Comments are invited on: (1) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Bonnie Poli, Chief, Pesticide Records Branch, Science and Technology, AMS, 8609 Sudley Road, Suite 203, Manassas, VA 20110. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: November 16, 2001.

Barry L. Carpenter,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 01–29181 Filed 11–21–01; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Slide Ridge Timber Sale Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Department of Agriculture, Forest Service, will prepare an Environmental Impact Statement (EIS) on a proposal to harvest timber in the Slide Ridge Timber Sale project area, Ketchikan-Misty Fiords Ranger District, Tongass National Forest. The proposed action includes a sale plan to harvest 4–5 million board feet (MMBF) or approximately 40% of the standing timber from 300 acres of National Forest System lands in the Whipple Creek drainage. No new roads would be built and approximately 6 miles of existing road would be reconstructed to facilitate helicopter yarding. The purpose and need of the timber sale is to contribute to the production of a sustained yield of timber and mix of other resource activities from the Tongass National Forest, consistent with Forest Plan Standards and Guidelines. A range of alternatives responsive to key issues will be developed. The range of alternatives will include the no-action alternative and an alternative that proposes up to 3 miles of new road construction to facilitate both helicopter and conventional yarding. The Tongass Forest Supervisor will decide on whether or not to harvest timber from this area, and if so, how this timber would be harvested. The decision will be based on the information disclosed in the EIS and the goals, objectives and desired future conditions as stated in the Forest Plan.

DATES: Opportunities for comment are available throughout the process. Individuals interested in receiving a scoping package should contact us within 30 days of the publication of this NOI. Additional opportunities for comment will be provided following development of a specific agency proposed action, during alternative development, and after release of the Draft EIS.

ADDRESSES: Please send written comments to District Ranger, Ketchikan-Misty Fiords Ranger District, 3031 Tongass Avenue, Ketchikan, AK 99901.

FOR FURTHER INFORMATION CONTACT: Jerry Ingersoll, District Ranger, (907) 228–4100 or Eric Trimble, Project Leader, (907) 228–4127.

SUPPLEMENTARY INFORMATION: The proposed timber sale is located within Tongass Forest Plan Value Comparison Units 7490 and 8642, Revillagigedo Island, Alaska. Approximately 80% of proposed sale units are located within the North Revilla Inventoried Roadless Area. The Forest Service is reevaluating its Roadless Area Conservation Rule (Roadless Rule) and is currently enjoined from implementing all aspects of the Roadless Rule by the U.S. District Court, District of Idaho. The Ketchikan-Misty Fiords Ranger District is preparing the Slide Ridge EIS to be consistent with the Forest Service Transportation; Final Administrative Policy (Roads Rule). Among other direction, the Roads Rule requires that an area-specific roads analysis to be completed and a determination of need for amendment or revision of the Forest Plan be made if any roads are to be constructed or reconstructed in inventoried roadless or contiguous unroaded areas, until a forest-wide roads analysis has been completed (FSM 7712.16(c)). This analysis and determination will be made for the Slide Ridge Timber Sale project. In *Sierra Club* v. *Lyons* (J00–0009 (CV)), the U.S. District Court, District of Alaska enjoined the Tongass National Forest from taking any action to change the wilderness character of any eligible roadless area until a supplemental environmental impact statement (SEIS) has been completed. The SEIS is currently being prepared. Planning for the Slide Ridge Timber Sale Project will continue simultaneously and in coordination with the SEIS. The repercussions of delaying the project planning process regarding road building and timber harvest, even for a relatively short period, can have a significant effect on the amount of timber available for sale in the next year. The Slide Ridge Timber Sale Project is consistent with the 1977 Tongass Land Management Plan.

Public participation has been and will continue to be an integral component of the analysis process. The Forest Service will be seeking additional information, comments, and assistance from Federal, State, local and tribal agencies, individuals and organizations that may be interested in, or affected by, proposed activities. The scoping process includes: (1) Identification of potential issues; (2) Identification of issues to be analyzed in depth; and (3) Suggestions for possible alternatives. Both written and verbal comments will be accepted during this process. A series of public meetings will be scheduled and a scoping package sent to interested individuals and/or organizations. Scoping began in January 2001 with a notice in the Ketchikan Daily News followed by a public mailing. At that time, we had anticipated preparing an Environmental Assessment (EA) for this project. As a result of the initial scoping we have decided to prepare an Environmental Impact Statement (EIS) that resulted in the publication of this NOI. Scoping will continue following this publication and through the preparation of the Draft EIS. Based on the results of scoping and the resource conditions within the project area, alternatives including a ''no action'' alternative will be developed for the Draft EIS. The Draft EIS is scheduled to be filed with the Environmental Protection Agency (EPA) in June 2002. The Final EIS is anticipated by January 2003. The comment period on the Draft EIS will be a minimum of 45 days from the date the Environmental Protection Agency (EPA) publishes the notice of availability (NOA) in the **Federal Register**.

The Forest Service believes that it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of Draft EIS must structure their participation in the environmental review of the

proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553, (1978). Also environmental objections that could have been raised at the Draft EIS stage may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2nd 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are received by the Forest Service at a time when it can meaningfully consider and respond to them in the Final EIS.

To assist the Forest Service in identifying and considering issues and concerns of the proposed action, comments during scoping and on the Draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the Draft EIS. Comments may also address the adequacy of the Draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality (CEQ) Regulations for implementing the procedural provisions of the National Environmental Policy Act (NEPA) at 40 CFR 1503.3 in addressing these points. Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR parts 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Requesters should be aware that, under FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within 7 days.

Permits required for implementation may include the following:

1. U.S. Army Corp of Engineers
   —Approval of discharge of dredged or fill material into the waters of the United States under section 404 of the Clean Water Act;
2. Environmental Protection Agency
   —National Pollutant Discharge Elimination System (402) Permit;
3. State of Alaska, Department of Environmental Conservation
   —Solid Waste Disposal Permit;
   —Certification of Compliance with Alaska Water Quality Standards

Thomas Puchlerz, Forest Supervisor, Tongass National Forest, Federal Building, Ketchikan, Alaska 99901, is the responsible official. The responsible official will consider the comments, response, disclosure of environmental consequences, and applicable laws, regulations, and policies in making the decision and stating the rationale in the Record of Decision.

Dated: November 13, 2001.

Thomas Puchlerz,

Forest Supervisor.

[FR Doc. 01–29215 Filed 11–21–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Northwest Sacramento Provincial Advisory Committee (SAC PAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Northwest Sacramento Provincial Advisory Committee (PAC) will meet on December 4, 2001, at Redding, California. The purpose of the meeting is a field trip to Iron Canyon to review fuel reduction activities in a Late Successional Reserve in keeping with the Northwest Forest Plan direction.

DATES: The meeting will be held December 4, 2001.

ADDRESSES: The meeting will be held at Forest Service Headquarters, 2400 Washington Ave., Redding, CA.

FOR FURTHER INFORMATION CONTACT: Jackie Riley, Committee Coordinator, USDA, Shasta-Trinity National Forest, 2400 Washington Ave., Redding, CA, 96001 (530) 242–2203; e-mail: *jriley01@fs.fed.us.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time. Support staff workloads resulted in a shorter than normal notice period.

Dated: November 16, 2001.

J. Sharon Heywood,

Forest Supervisor.

[FR Doc. 01–29214 Filed 11–21–01; 8:45 am]

BILLING CODE 3410–FK–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: December 24, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly (703) 603–7740.

SUPPLEMENTARY INFORMATION: On August 17, September 21, September 28, and October 9, 2001, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (66 FR 43180, 48661, 49615 and 51372) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodity and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity and services.

3. The action will result in authorizing small entities to furnish the

commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List.

Accordingly, the following commodity and services are added to the Procurement List:

Commodity:

Cheesecloth
8305–00–205–3558

Services:

Central Facility Management, Veterans Affairs Headquarters Building, Washington, DC; Janitorial/Custodial, El Centro Toilet Cleaning, Bureau of Land Management, Imperial County, California; Janitorial/Custodial, Special Processing (Detention) Center, U.S. Immigration & Naturalization Service, Ramey, Puerto Rico; Laundry Service, R. E. Bush Naval Hospital, Twenty-nine Palms, California.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 01–29255 Filed 11–21–01; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete commodities previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: December 24, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice for each service will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Base Supply Center, Department of the Army, Fort Leavenworth, Kansas
NPA: Envision, Inc., Wichita, Kansas.
Government Agency: Fort Leavenworth, Kansas, Janitorial/Custodial, Defense Commissary Agency, Western Pacific Region, McClellan, California.
NPA: PRIDE Industries, Roseville, California.
Government Agency: Defense Commissary Agency, Janitorial/Custodial, Missouri Air National Guard, 10800 Lambert International Boulevard, Bridgeton, Missouri.
NPA: MGI Services Corporation, St. Louis, Missouri.
Government Agency: Missouri Air National Guard, Janitorial/Custodial, Naval Reserve Readiness Command, Regional North Central, 715 Apollo Avenue, Minneapolis, Minnesota.
NPA: AccessAbility, Inc., Minneapolis, Minnesota.
Government Agency: Naval Facilities Engineering Command, Janitorial/Custodial, U.S. Marshals Service, Will Rogers World Airport, 5900 Air Cargo Road, Oklahoma City, Oklahoma.
NPA: The Oklahoma League for the Blind, Oklahoma City, Oklahoma.
Government Agency: U.S. Marshals Service, Office Supply Store, At the following locations:
Defense Supply Service—Washington, Hoffman Building II, Alexandria, Virginia;
Defense Supply Service—Washington, Army Material Command, Alexandria, Virginia;
Defense Supply Service—Washington, Pentagon, Rooms 1E700 and 3C157, Washington, DC.
NPA: Virginia Industries for the Blind, Richmond, Virginia.
Government Agency: Defense Supply Service—Washington.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the commodities to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for deletion from the Procurement List.

The following commodities are proposed for deletion from the Procurement List:

Commodities

Tissue, Facial
8540–00–900–4891
Sheath, Ax
8465–01–110–2078
Sheath, Brush Hook (Brush)
8465–01–136–4720

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 01–29256 Filed 11–21–01; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Addition; Corrections

In the document appearing on page 56634, FR Doc. 01–28211, in the issue of November 9, 2001, in the third column the Committee published a notice of deletions to the Procurement List of, among other things, Enamel, Lacquer, National Stock Number (NSN) 8010–00–942–8712. This notice is amended to correct the NSN to 8010–00–941–8712.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 01–29257 Filed 11–21–01; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–821, A–588–837]

Large Newspaper Printing Presses and Components From Germany and Japan: Extension of Time Limit for Preliminary and Final Results of Five-Year Sunset Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for preliminary and final results of five-year (''sunset'') reviews; large newspaper printing presses and components from Germany and Japan.

SUMMARY: The Department of Commerce (''the Department'') is extending the time limit for preliminary and final results in the full sunset review of the antidumping duty order on large newspaper printing presses and components (LNPPs) from Germany.[1] In addition, we are aligning and extending the expedited sunset review on LNPPs from Japan with the full sunset review of the antidumping duty order on LNPPs from Germany in order to address an issue concerning domestic interested party response—an issue relevant in both proceedings.[2] As a result, although not required under the statute or regulations, the Department intends to issue preliminary results on LNPPs from Japan along with the preliminary results on LNPPs from Germany not later than February 19, 2002. In addition the Department intends to issue its final results in both reviews, not later than June 27, 2002.

EFFECTIVE DATE: November 23, 2001.

FOR FURTHER INFORMATION CONTACT: Martha V. Douthit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–5050.

[1] The Department normally will issue its preliminary results in a full sunset review not later than 110 days after the date of publication in the **Federal Register** of the notice of initiation. However, if the Secretary determines that a full sunset review is extraordinarily complicated under section 751(c)(5)(C) of the Act, the Secretary may extend the period for issuing final results by not more than 90 days (see section 751(c)(5)(B) of the Act).

[2] Section 751(c)(2)(B) of the Act provides that the Department ''may issue'' a final determination in an expedited sunset review within 120 days after initiation. The Department has the discretion to determine whether it will conduct an expedited review within 120 days.

Extension of Preliminary and Final Results

On August 1, 2001, the Department initiated (66 FR 39731) sunset reviews of the antidumping duty orders on LNPPs from Germany and Japan. In the Germany review, the Department had determined that a full (240 day) sunset review was warranted. The Department has now determined that it also is appropriate to take the maximum amount of time allowed under the statute to conduct the Japan sunset review. In the sunset review of the antidumping duty order on LNPPs from Japan, the Department had determined to conduct an expedited sunset review because no respondent interested party had filed a substantive response expressing interest in the order. Since that time, however, an issue has arisen in the German review, concerning the adequacy of the domestic interested party response that is relevant to the Japan case as well, *i.e.* the domestic interested party is the same in both cases. Therefore, we are aligning the deadlines to the sunset review on LNPPs from Japan, with the full sunset review on LNPPs from Germany.

The Department also has determined to extend the 240 day deadline in both sunset reviews, because, as a result of the domestic interested party adequacy issue, we find they are extraordinarily complicated. We are therefore extending the period for issuing preliminary and final results by 90 days (see section 751(c)(5)(B) of the Act). Thus, the Department intends to issue the preliminary and final results on LNPPs from Germany and Japan, not later than February 19, 2002 and June 27, 2002, respectively, in accordance with section 751(c)(5)(B) of the Act.

Dated: November 16, 2001.

Faryar Shirzad,

Assistant Secretary for Import Administration.

[FR Doc. 01–29277 Filed 11–21–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Department of the Navy

Record of Decision for the Yuma Training Range Complex, Arizona and California

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(c) of the National Environmental Policy Act (NEPA) of 1969, and the Council on Environmental Quality regulations (40 CFR parts 1500–1508), the Department of the Navy has reevaluated the potential for cumulative effects on Sonoran pronghorn in a Supplemental Environmental Impact Statement (SEIS) and announces its decision to continue upgrading the capability of the Yuma Training Range Complex (YTRC).

ADDRESSES: Questions regarding the SEIS prepared for this action may be directed to Commander, Southwest Division, Naval Facilities Engineering Command, 1220 Pacific Highway, San Diego, CA 92132–5190 (Attn: Ms. Deb Theroux).

FOR FURTHER INFORMATION CONTACT: Ms. Deb Theroux, telephone (619) 532–1162.

SUPPLEMENTARY INFORMATION: The Marine Corps completed an Environmental Impact Statement (EIS) in 1997 addressing its military aviation and associated training impacts on the YTRC. This Complex includes portions of the Barry M. Goldwater Range, AZ, which contains habitat for the Sonoran pronghorn (Antilocapra americana sonoriensis), an endangered species.

On February 12, 2001, the United States District Court for the District of Columbia found the cumulative impact analysis in the 1997 YTRC EIS deficient in that it failed to provide sufficient analysis of cumulative impacts on the Sonoran pronghorn in accordance with 40 CFR 1508.7. The court remanded the matter to the Marine Corps for further consideration of such impacts. The court also found the Biological Opinion rendered by the U.S. Fish and Wildlife Service (USFWS) pursuant to section 7 of the Endangered Species Act addressing actions described in the 1997 EIS deficient in that it failed to provide sufficient analysis of cumulative impacts on the Sonoran pronghorn. The court remanded the Biological Opinion to USFWS for further consideration of such impacts.

The Department of the Navy prepared a supplement to the EIS, in accordance with 40 CFR 1502.9(c), that evaluates the cumulative impacts on the Sonoran pronghorn of Marine Corps actions when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Also, USFWS reissued the Biological Opinion addressing upgrade of the YTRC based in part on new information provided by the Marine Corps developed during preparation of the SEIS.

Based upon the new Biological Opinion issued by the USFWS and the analysis of cumulative effects in the Supplemental EIS, the Department of the Navy has determined there is no need to amend the actions selected for

implementation in the Record of Decision published in the **Federal Register** on October 2, 1998. Actions approved in this decision will continue to be implemented as funds become available. However, additional mitigation measures identified in the Biological Opinion and Final SEIS will be made a part of the approved actions. Therefore, the October 2, 1998, Record of Decision is modified, as discussed in the following paragraphs, to address the cumulative effects analysis discussed in the SEIS and incorporate additional mitigation measures.

Cumulative Effects and Other Actions Considered

Cumulative effects are those additive or interactive effects that would result from the incremental impact of the proposed actions when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions. In accordance with the Court's order, the purpose of the SEIS is limited to a reconsideration of the cumulative impacts of the proposed actions and alternatives examined in the YTRC FEIS together with other relevant past, present, and reasonably foreseeable future actions on Sonoran pronghorn.

Through coordination with agencies operating within and having management responsibilities in the region within the current distribution of Sonoran pronghorn, 68 past, present, and reasonably foreseeable future actions were identified. Examples of other actions considered included past mining and ranching, transportation and utility corridors, recreation, agriculture, scientific research, patrol for undocumented aliens, military activities conducted by the Air Force and other branches of service, and proposed residential developments.

All of the YTRC alternatives as well as the 68 other past, present, and reasonably future actions were evaluated using criteria derived from the five delisting factors established in the Endangered Species Act. The evaluation criteria included the following:

—Habitat loss or curtailment, including barriers or impediments to movement or access to habitat.
—Habitat modification or diminished quality of habitat, including habitat fragmentation and degraded air quality.
—Overutilization (e.g., hunting and research activities) of Sonoran pronghorn.
—Disease and predation, including the potential of increasing predator populations or opportunities for predators to prey on Sonoran pronghorn.
—Management or regulatory conflicts.
—Death or injury of Sonoran pronghorn, including potential death or injury from collisions with vehicles, and munitions delivery or detonations.
—Harassment of Sonoran pronghorn, including surface vehicles, human presence, surface noise sources, overflight noise, and visual presence of aircraft.
—Diminished fawn recruitment.
—Exposure to toxic substances or materials, including toxins found in forage plants or surface water and exposure to harmful radio frequency energy.

In addition, actions in the region (including those within the Chocolate Mountain Range), but outside of the current distribution area of the Sonoran pronghorn, were evaluated for their potential to influence a change that could affect Sonoran pronghorn or its habitat. Actions in the region were also evaluated for their potential to result in an environmental effect that might be transported or transferred (for example, by water runoff or wind) into the current distribution area of the Sonoran pronghorn.

The following summarizes the SEIS findings of the analysis of the potential cumulative effects on Sonoran pronghorn resulting from the YTRC actions combined with and other past, present, and reasonably foreseeable future actions:

—The cumulative effects of past actions and climatic factors reduced the range and size of the Sonoran pronghorn population to its current endangered status. The limited range of this subspecies, its division into three isolated subpopulations, and its relatively small population size exacerbate effects of currently active factors.
—The Sonoran pronghorn is not threatened with further significant habitat loss or degradation as a result of current or reasonably foreseeable future actions.
—The timing, distribution, and abundance of rainfall—above all other currently active factors and activities—control the prospect for the long-term survival and potential recovery of the Sonoran pronghorn through the influence of precipitation patterns on the availability of adequate forage.
—A near-term threat to the continued survival of the Sonoran pronghorn without significant management intervention is the advancing age of its current population. More than half of the existing population will likely die over the next two to three years of advanced age factors even with favorable rainfall and forage production. Adequate rainfall and forage production is essential over this same period if the losses of older animals are to be offset by fawn recruitment.
—Sonoran pronghorn casualties have occurred as a result of the capture and radio-collaring program. However, the risks of death or injury of Sonoran pronghorn from munitions delivery training and vehicle use are manageable and have not posed significant incremental impacts on this subspecies.
—No cumulative impacts on the U.S. Sonoran pronghorn population were found to be occurring as a result of hunting, abnormal disease or predation rates induced by human activities, management or regulatory conflicts, or exposure to toxic substances or materials.
—Marine Corps air and surface activities within the BMGR, and within the restricted airspace overlying the Cabeza Prieta NWR have contributed some incremental, adverse effects to the overall cumulative impacts on Sonoran pronghorn. These effects, however, are of negligible magnitudes and none are significant.

Mitigation

The original 1997 YTRC FEIS includes ongoing procedures that the Marine Corps implements to help protect environmental resources and mitigation measures to be applied in response to implementation of the proposed actions. These mitigation measures shall continue to be implemented.

Based on the findings of the SEIS, the Marine Corps commits to implementing the following additional mitigation measures:

—In coordination with other federal agencies, the Marine Corps will study the potential effects of chaff on Sonoran pronghorn with an emphasis on the possible toxic conditions of chaff contamination in waters located on the Barry M. Goldwater Range and Cabeza Prieta National Wildlife Refuge. By the middle of fiscal year 2002, a study design will be provided to the USFWS for approval. If adverse effects are identified, the report on the study will include recommendations for reducing or eliminating adverse effects of chaff on Sonoran pronghorn. In coordination with the USFWS, the Marine Corps will implement the

recommendations within two years of the date of the final report.

—The Marine Corps will support its fair share of the 51 management and research projects developed by the Sonoran Pronghorn Recovery Team to promote recovery of the subspecies. These projects may be conducted in coordination with other agencies. Projects will be implemented beginning in fiscal years 2002 and 2003 to the extent that funding is available.

—The Marine Corps will provide the USFWS Phoenix Ecological Services Office and the Cabeza Prieta National Wildlife Refuge with an annual monitoring report that provides information on the prior year's implementation progress for the mitigation measures described above as well as any terms and conditions or reasonable and prudent alternatives listed in the Biological Opinion. The report will also include the date and location of any Sonoran pronghorn observed by Marine Corps personnel, including observations of injured or dead Sonoran pronghorn. Reports that may be produced in association with implementation of the mitigation measures or the Biological Opinion will be appended to the annual monitoring report. The first annual report will be submitted by 1 March 2002.

—The Marine Corps will support closure of the Mohawk Valley area of BMGR—West to public use from 15 March to 15 July beginning in 2002 to reduce the potential for human disturbance of Sonoran pronghorn during the period that is critical to early fawn survival. The Marine Corps will also support the permanent closure of roads within this area that are not needed for administrative agency use. The roads selected for closures will be identified by 1 October 2002 through consultation with the USFWS and other agency partners participating in the ongoing development of the Barry M. Goldwater Range Integrated Natural Resources Management Plan. By 15 March 2003, routes will be signed, and permanently closed routes will be blocked with physical barriers. The Marine Corps will construct an interpretive kiosk at the entrance to Barry M. Goldwater Range on the road from Tacna. Text for the kiosk will be prepared in coordination with USFWS and will describe regulations for public use of the range.

Biological Opinion

As noted earlier, USFWS issued a new Biological Opinion addressing the YTRC upgrades. USFWS determined the action will not jeopardize the existence of the Sonoran pronghorn. USFWS believes low-level helicopter use should avoid areas of significant pronghorn use to minimize adverse effects from helicopters on the pronghorn and its habitat, particularly areas important for fawns and their mothers. Accordingly, USFWS issued two terms and conditions regarding low-level helicopter use: one low-level route utilized by helicopters over the Cabeza Prieta National Wildlife Refuge should be modified in order to further reduce impacts on the Sonoran pronghorn, all helicopters between March 15 and July 15 of year year, except those participating in the Weapons Tactics Instructors course, should remain west of the current range of the Sonoran pronghorn, or on designated transit routes, or above 1,000 feet above ground level. These terms and conditions will be implemented. USFWS anticipates that no more than 6 Sonoran pronghorns could be taken as an incidental result of the proposed action. The incidental take is expected to be in the form of harassment. This incidental take provision will be reviewed concurrent with subsequent reviews of the Barry M. Goldwater Range Integrated Natural Resources Management Plan. Said reviews are required every five years.

Conclusion

All practicable means to avoid or minimize environmental harm from implementing the upgrades to the YTRC have been considered. After considering the requirements of the Marine Corps, the potential environmental impacts of this action, social and economic concerns, and all comments received during the EIS process, I have determined that the decisions made pursuant to the 1997 YTRC FEIS shall proceed as discussed in the SEIS, and that Marine Corps actions to manage the western portion of the Barry M. Goldwater Range for military aviation activities, when added to other past, present, and reasonably foreseeable future actions, will not have cumulative significant impacts on the Sonoran pronghorn.

Dated: November 16, 2001.

Duncan Holaday,

Deputy Assistant Secretary of the Navy, (Installations and Facilities).

[FR Doc. 01–29276 Filed 11–21–01; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Arbitration Panel Decision Under the Randolph-Sheppard Act

AGENCY: Department of Education.

ACTION: Notice of arbitration panel decision under the Randolph-Sheppard Act.

SUMMARY: Notice is hereby given that on May 19, 2001, an arbitration panel rendered a decision in the matter of *Donna Evans, et al* v. *Maryland Division of Rehabilitation Services (Docket No. R–S/99–5).* This panel was convened by the U.S. Department of Education pursuant to 20 U.S.C. 107d-1(a) upon receipt of a complaint filed by petitioner, Donna Evans, et al.

FOR FURTHER INFORMATION: A copy of the full text of the arbitration panel decision may be obtained from Suzette E. Haynes, U.S. Department of Education, 400 Maryland Avenue, SW., room 3232, Mary E. Switzer Building, Washington, DC 20202–2738. Telephone: (202) 205–8536. If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205–8298.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site:
www.ed.gov/legislation/FedRegister

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html*

SUPPLEMENTARY INFORMATION: Pursuant to section 6(c) of the Randolph-Sheppard Act (the Act) 20 U.S.C. 107d-2(c), the Secretary publishes in the **Federal Register** a synopsis of each arbitration panel decision affecting the administration of vending facilities on Federal and other property.

Background

This dispute concerns the alleged failure by the Maryland Division of Rehabilitation Services, the State licensing agency (SLA), to properly administer the Randolph-Sheppard Vending Facility Program by prohibiting the State Committee of Blind Vendors (Committee), who are the complainants in this case, from using allocated funds to pay legal expenses. As a result, the Committee maintained that it had been restricted in participating in the administration of the SLA's Randolph-Sheppard Vending Facility Program pursuant to the provisions of the Act (20 U.S.C. 107 *et seq.*) and the implementing regulations in 34 CFR part 395.

A summary of the facts is as follows: In August 1997 the Committee voted to ask for an increase in its budget, which included funds for legal counsel. In a letter dated September 18, 1997, to the Committee, the SLA denied the increase stating three reasons, which were—(1) no significant revenue enhancements had been demonstrated for the FY 1998 and FY 1999 budget year; (2) many of the major budget items were driven by the settlement agreements; and (3) the SLA's Randolph-Sheppard Vending Facility Program had significantly reduced program costs by eliminating two positions. The SLA further stated that, based on a review of the Randolph-Sheppard Vending Facility Program, the SLA would initiate a modest increase in the Committee's budget that was previously approved for FY 1998 and FY 1999.

The issue of the use of funds for legal expenses budgeted for the Committee was addressed in a letter dated October 1, 1997, from the Chairman of the Committee to the SLA. The Chairman indicated that it was the Committee's understanding that both parties had a consensus concerning the use of funds for legal counsel. The Committee alleged that the SLA never submitted to the Committee in writing any formal objection to the use of the Committee's funds for legal fees. The Committee also alleged that there is no prohibition in the Act and implementing regulations concerning the use of legal counsel by the Committee; therefore, the Committee was entitled to use its funds for legal representation.

The Committee further alleged that a request for a full evidentiary hearing on their complaint concerning the SLA's refusal of payment of legal fees was filed on July 12, 1998, with the SLA. On August 3, 1998, the SLA informed the Committee through the Office of Administrative Hearings that a pre-hearing conference date had been set for October 1, 1998. However, the Committee maintained that the delay in providing a full evidentiary hearing violated the Act, implementing regulations, Maryland State regulations, and the Committee's due process rights to a speedy resolution of its complaint.

The Committee also challenged the selection of the individual to chair the administrative review conference required by State regulations with respect to vendor complaints and challenged the attendance at those informal conferences of the SLA's attorney.

Arbitration Panel Decision

A majority of the arbitration panel concluded that, while the Committee had raised a number of interesting policy issues in support of their claims, there was no requirement in the Act or the implementing Federal or State regulations to fund the activities of the Committee, to grant the Committee plenary control over the expenditures of any monies budgeted to it by the SLA, or to require that the SLA pay for the attorney fees of the Committee, even if those fees were incurred in furtherance of Committee activities mandated by the Act.

The panel further found that the 1974 Amendments to the Act imposed certain responsibilities upon the Committee and increased the participation of licensed blind vendors in the conduct of the Randolph-Sheppard Vending Facility Program. However, the panel ruled that the Act did not grant the Committee any control over the expenditure of program funds (including those program funds that have their source in vendor activities or activities engaged in for the benefit of vendors) and thus did not mandate that the SLA fund any Committee activities in particular.

Concerning the dissatisfaction of the Committee regarding the Administrative Review Conference, the majority of the panel concluded that the selection of the chair and the manner in which the conference was held was consistent with the applicable State regulations.

One panel member dissented.

The views and opinions expressed by the panel do not necessarily represent the views and opinions of the U.S. Department of Education.

Dated: November 16, 2001.

Robert H. Pasternack,

Assistant Secretary, Office Special of Education and Rehabilitative Services.

[FR Doc. 01–29200 Filed 11–21–01; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF ENERGY

National Energy Technology Laboratory; Notice of Availability of a Financial Assistance Solicitation

AGENCY: National Energy Technology Laboratory (NETL), Morgantown, Department of Energy (DOE).

ACTION: Notice of availability of a Financial Assistance Solicitation.

SUMMARY: NETL announces that, pursuant to 10 CFR 600.8(a)(2), and in support of advanced coal research to U.S. colleges and universities, it intends to conduct a competitive Program Solicitation No. DE–PS26–02NT41369 and award financial assistance grants to qualified recipients. Applications will be subjected to a comparative merit review by a technical panel of DOE subject-matter experts and external peer reviewers. Awards will be made to a limited number of proposers based on: The scientific merit of the proposals, application of relevant program policy factors, and the availability of funds.

Once released, the solicitation will be available for downloading from the IIPS Internet page. At this internet site you will be able to register with IIPS, enabling you to download the solicitation and to submit a proposal. If you need technical assistance in registering or for any other IIPS function call the IIPS Help Desk at (800) 683–0751 or email the Help Desk personnel at *IIPS__HelpDesk@e-center.doe.gov.* Questions relating to the solicitation content must be submitted electronically to the Contract Specialist via email. All responses to questions will be released on the IIPS home page as will all amendments. The solicitation will only be available in IIPS.

DATES: The solicitation will be available for downloading on the DOE/NETL's Homepage at *http://www.netl.doe.gov/business* and the IIPS ''Industry Interactive Procurement System'' Internet page located at *http://e-center.doe.gov* on or about December 3, 2001. Applications must be prepared and submitted in accordance with the instructions in the Program Solicitation and must be received at NETL by January 16, 2002. Prior to submitting your application to the solicitation, periodically check the NETL Website for any amendments.

FOR FURTHER SOLICITATION INFORMATION CONTACT: Michael P. Nolan, U.S. Department of Energy, National Energy Technology Laboratory, P.O. Box 880 (MS I07), Morgantown, WV 26507–0880; Telephone: 304/285–4149; Facsimile: 304/285–4683; E-mail: *mnolan@netl.doe.gov.*

SUPPLEMENTARY INFORMATION: Through Program Solicitation DE–PS26–02NT41369, the DOE is interested in applications from U.S. colleges and universities, and university-affiliated research centers submitting applications through their respective universities. Applications will be selected to complement and enhance research being conducted in related Fossil Energy programs. Applications may be submitted individually (*i.e.,* by only one college/university or one college subcontracting with one other college/university) or jointly (*i.e.,* by ''teams'' made up of (1) three or more colleges/universities, or (2) two or more colleges/universities and at least one industrial partner. Collaboration, in the form of joint proposals, is *encouraged* but not required.

Eligibility

Applications submitted in response to this solicitation must address coal research in one of the key focus areas of the Core Program or as outlined in the Innovative Concepts Phase-I & Phase-II Programs.

Background

The current landscape of the U.S. energy industry, not unlike that in other parts of the world, is undergoing a transformation driven by changes such as deregulation of power generation, more stringent environmental standards and regulations, climate change concerns, and other market forces. With these changes come new players and a refocusing of existing players in providing energy services and products. The traditional settings of how energy (both electricity and fuel) is generated, transported, and utilized are likely to be very different in the coming decades. As market, policy, and regulatory forces evolve and shape the energy industry both domestically and globally, the opportunity exists for universities, government, and industry partnerships to invest in advanced fossil energy technologies that can return public and economic benefits many times over. These benefits are achievable through the development of advanced coal technologies for the marketplace.

Energy from coal-fired powerplants will continue to play a dominant role as an energy source, and therefore, it is prudent to use this resource wisely and ensure that it remains part of the sustainable energy solution. In that regard, our focus is on a concept we call Vision 21. Vision 21 is a pathway to clean, affordable energy achieved through a combination of technology evolution and innovation aimed at creating the most advanced fleet of flexible, clean and efficient power and energy plants for the 21st century. Clean, efficient, competitively priced coal-derived products, and low-cost environmental compliance and energy systems remain key to our continuing prosperity and our commitment to tackle environmental challenges, including climate change. It is envisioned that these Vision 21 plants can competitively produce low-cost electricity at efficiencies higher than 60% with coal. This class of facilities will involve ''near-zero discharge'' energy plants—virtually no emissions will escape into the environment. Sulfur dioxide and nitrogen oxide pollutants would be removed and converted into environmentally benign substances, perhaps fertilizers or other commercial products. Carbon dioxide could be (1) concentrated and either recycled or disposed of in a geologically permanent manner, or (2) converted into industrially useful products, or (3) by creating offsetting natural sinks for CO_2.

Clean coal-fired powerplants remain the major source of electricity for the world while distributed generation, including renewables, will assume a growing share of the energy market. Technological advances finding their way into future markets could result in advanced co-production and co-processing facilities around the world, based upon Vision 21 technologies developed through universities, government, and industry partnerships.

This Vision 21 concept, in many ways is the culmination of decades of power and fuels research and development. Within the Vision 21 plants, the full energy potential of fossil fuel feedstocks and ''opportunity'' feedstocks such as biomass, petroleum coke, and other materials that might otherwise be considered as wastes, can be tapped by integrating advanced technology ''modules.'' These technology modules include fuel-flexible coal gasifiers and combustors, gas for fuels and chemical synthesis. Each Vision 21 plant can be built in the configuration best suited for its market application by combining technology modules. Designers of Vision 21 plant would tailor the plant to use the desired feedstocks and produce the desired products by selecting and integrating the appropriate ''technology modules.''

The goal of Vision 21 is to effectively eliminate, at competitive costs, environmental concerns associated with the use of fossil fuel for producing electricity and transportation fuels. Vision 21 is based on three premises: that we will need to rely on fossil fuels for a major share of our electricity and transportation fuel needs well into the 21st century; that it makes sense to rely on a diverse mix of energy resources, including coal, gas, oil, biomass and other renewables, nuclear, and so-called ''opportunity'' resources, rather than on a reduced subset of these resources; and that R&D directed at resolving our energy and environmental issues can find affordable ways to make energy conversion systems meet even stricter environmental standards.

To accomplish the program objective, applications will be accepted in three program areas: (1) The Core Program, (2) the Innovative Concepts Phase-I Program, and (3) the Innovative Concepts Phase-II Program.

University Coal Research (UCR) Core Program Focus Areas

To develop and sustain a national program of university research in fundamental coal studies, the DOE is interested in innovative and fundamental research pertinent to coal conversion and utilization. The maximum DOE funding for each individual college/university award under the University Coal Research Core Program is:

12 month project period	$80,000 (max. DOE funds)
13–24 month project period	$140,000 (max. DOE funds)
25–60 month project period	$200,000 (max. DOE funds)

For Joint Universities and Joint University/Industry awards, the maximum DOE funding is $400,000 for a 36-month performance period. Joint University/Industry applications must specify a minimum of twenty-five percent (25%) cost sharing of the total proposed project cost.

The DOE anticipates funding at least one proposal in each focus area under the UCR Core Program; however, high-quality proposals in a higher ranked

focus area may be given more consideration during the selection process. Research in this area is *limited* to the following six (6) focus areas and is listed numerically in descending order of programmatic priority.

Core Program Focus Areas

1.0 Novel Sensors and Control Systems

Novel sensors and control systems that support the full-scale implementation and operations of highly efficient power generation technologies are of interest, these systems include: advanced combustion, gasification, turbines, and fuel cells, as well as gas cleaning technologies, carbon sequestration, and advanced emissions control technologies. Current technology developments are supported by the Vision 21 program and other programmatic efforts aimed at enhancing the efficiency and reducing emissions, thereby removing the environmental concerns associated with fossil fuel use. To facilitate this effort, several ''smart'' sensors and advanced control algorithms are needed to operate these complex, integrated technologies in a safe and reliable manner.

Grant applications for novel sensor techniques are sought that can operate reliably and accurately in the presence of high temperature (e.g., 1000 °C or higher), elevated pressure (*e.g.*, 100–1000 psig), abrasive streams (*e.g.*, high particulate flue gas) and corrosive atmospheres (*e.g.*, oxidizing and reducing conditions). Robust sensors for in-situ monitoring of fine particulates (*e.g.*, 0–10 microns), environmental contaminants (*e.g.*, NO_X), and gases (*e.g.*, hydrogen, NH_3) are needed. Novel approaches to on-line characterization of solid fuel (*e.g.*, coal, biomass) are needed to measure parameters such as: feed rates; heating value; percent water content; ash; sulfur, nitrogen concentrations; and trace elemental contaminants. Robust temperature-sensing techniques and instrumentation are needed for use in coal gasifiers (up to 2600 °C in reducing atmospheres) and gas turbines (up to 4000 °C in oxidizing atmospheres).

In addition to sensors that monitor the operation of advanced and existing power generation technologies, grant applications are sought for instrumentation and sensors to monitor a system's ''health'' status on-line. Techniques are needed to monitor and predict maintenance of critical equipment. Examples of system health monitoring needs include techniques to indicate or measure (1) refractory wear in coal gasfiers, (2) thermal barrier coating degradation in natural gas turbines, and (3) water-wall wastage associated with low- NO_X burner technology.

2.0 Materials and Components for Vision 21 Systems

Gas turbines and membrane reactors are among the enabling technologies that support the Vision 21 concept. Membrane reactor development represents a critical enabling technology for future Vision 21 Systems. Of particular interest are materials needs and property changes to accommodate coal and bio-mass fuels.

Membrane reactors based on microporous and mesoporous ceramic membranes provide a broad array of opportunities regarding the choice materials for membranes, their catalytic properties and possible applications. The most widely used application involves equilibrium displacement by removal of at least one reaction product. Most often, the removal of hydrogen in dehydrogenation or water gas shift reactions has been the process of choice.

Porous ceramic membranes can be made, in whole or in part, of alumina, silica, titania, zirconia, zeolites, etc., materials which are catalytically active under suitable operating conditions. During preparation procedure one can give specific properties to the catalyst; *e.g.*, successive layers of different materials can be deposited across the membrane radius which would allow one to carry out different consecutive reactions in different regions of the membrane.

The prospects of using dense membranes based on mixed ionic/electronic conducting ceramics for syngas production in a catalytic membrane reactor are constrained by problems related to limited thermodynamic stability and poor dimensional stability of candidate materials. New compositions of oxygen transport membrane materials within or outside of Perovskitic (ABO_3) and Brownmillerite ($A_2B_2O_5$) structures for separation of oxygen via oxygen anion and electron conduction should be investigated to address the issues. Proton conducting ceramics are also of interest.

In the area of materials for fuel-flexible combustion turbines, an implication of high efficiency is that materials with very high temperature capabilities will be necessary. Practical application of metals and coatings, as structural materials at the ultrahigh temperatures (well above 1000°C) required is a formidable challenge. Among the topics of interest are the following:

Grant applications are sought for proposals to develop catalytic membrane reactors to circumvent thermodynamic equilibrium limitations and derive useful products such as hydrogen from reactants obtained from coal conversion or gasification. Novel membrane materials and reactor configurations as well as new applications to different reaction systems are desired.

Research leading to optimization of single crystal alloys for gas turbine airfoils and modifications that will better tailor the alloy properties to the duty cycle requirements and processing constraints of advanced land-based gas turbines, while building on the technology embodied in current superalloys. Such a modified alloy would have the combination of very long-term mechanical properties and environmental resistance required for advanced gas turbine conditions.

Advanced thermal barrier coatings (TBCs) that have superior durability and performance in an industrial gas turbine environment. Desirable characteristics include TBC compositions resistant to corrosive attack by deposits derived from combustion of low-grade fuel, syngas, and air impurities, and/or sealed gas path surfaces to inhibit deposits from penetrating into the TBCs porous (strain tolerant) microstructure, as well as lower thermal conductivity. Also, develop methods to identify and avoid combustion environments that result in unacceptable TBC life. The research should include modeling and prediction of the rate of fuel ash deposition onto turbine airfoils and the corrosiveness of ash deposits to YSZ and other TBC candidates.

3.0 Computational Approaches to Advanced Catalyst Design

Improvements in catalysts are needed to reduce the cost of producing transportation fuels suitable for use under forthcoming stricter environmental regulations and to broaden the base of feedstocks available for their production. Two examples of particular concern of this solicitation are Fischer Tropsch synthesis and catalytic reforming. The Fischer Tropsch synthesis produces a paraffinic wax that may then be cracked to produce a sulfur-free, aromatic-free, and high cetane diesel fuel. This fuel is a desirable blending stock that can be used to bring diesel fuels within the more strict future regulations on sulfur and aromatics content. A major draw back to the Fischer Tropsch synthesis is that the lack of selectivity of the current catalysts results in a wide distribution of molecular weight in the product slate.

Expensive post-synthesis processing is then required that drives up the price of the desired diesel fuel. An ideal Fischer Tropsch synthesis would produce a narrow distillate cut that falls within the diesel range with little production of unwanted byproduct. Catalytic reforming of natural gas is the first step in converting this under-utilized natural resource to liquid fuels. In this case, a major problem lies in the tendency of the catalyst to form carbonaceous deposits that either reduces its lifetime or places restrictions on process operating parameters. The ever-increasing power of the methods and hardware now being applied in computational chemistry needs to be enlisted to help develop better catalysts for both of these processes. Of most value are studies that provide guidance in the means to improve catalyst design through choice of metals, alloys, promoters, supports, size of the active particles, etc.

To provide the fundamental knowledge required to effectively accelerate these efforts in catalyst development, grant applications are sought for the application of computational methods to generate a molecular understanding of the kinetics of competitive reactions on catalytic surfaces. Successful applications will attack the most critical problems in catalyst performance. Applications must show evidence of the intent to develop means to improve catalyst performance through strategies such as: the suppression of the relative rates of surface reactions leading to deactivation, suppression of the production of unwanted co-products, or enhancement of the control of selectivity towards production of desirable products. Grant applications must specifically address either of two problems: determination of the molecular principles that govern the relative rates of chain growth versus chain termination ($\propto\leq$) on iron or cobalt Fischer Tropsch catalysts, or determination of the molecular factors that govern the relative rates of coke formation versus methane reforming on nickel catalysts. The proposals must be conceived at the fundamental molecular level. Applications based on reactor or process modeling will not be considered.

4.0 Materials for Intermediate Temperature Solid-Oxide Fuel Cells

Solid-oxide fuel cells (SOFCs) offer significant advantages in the conversion of fossil fuels to electrical power. Without an intermediate heat production step the efficiency of an SOFC can be much higher than current methods of producing power. Currently, SOFC configurations and applications are restricted by the high-temperatures needed to maintain adequate area specific resistanceses while ensuring long-term reliability. The only material set (yttria stabilized zirconia, lanthanum strontium manganite, and nickel/zirconia cermet) that has been successfully demonstrated over a substantial period of time has a lower temperature limit of about 800 °C and possibly 750°C with some modifications.

Grant applications are being sought for identification and characterization of one or more (considering the time and financial constraints) SOFC anode, electrolyte, cathode material set(s) that can operate in the 500°C to 700°C range. The structure(s) should be manufacturable with relatively inexpensive manufacturing techniques. The material cost should be roughly no more than the previously referenced material set or less. (Electrolyte transference numbers should be known or shown to be adequate in a typical SOFC environment before proceeding). The characterization should demonstrate as much as possible that the complete structure can meet the requirements of an SOFC fuel cell with a projected power density of (0.6W/cm^2 at 0.7 V, corrected for test cell resistance) in the indicated temperature range and subject to the typical fuel and oxidant environments. Characterization should include chemical stability between the components. The lifetime effects (phase stability, thermal expansion compatibility, conductivity aging, and electrode sintering) should be considered and characterized as much as possible. The characterization of the material set should in general be, as complete as possible and, not duplicate publicly known information. The proposal should address all aspects of the stated topic.

5.0 Novel Concepts for Reducing Water Used in Power Generation

Power generated from fossil fuels, especially coal, is dependent on water. On average, approximately 30 gallons of water are required for each kWh of power produced from coal. Around 70 trillion gallons of water are consumed or impacted annually in the United States to produce energy. The large quantity of water to produce power has regulatory and technological issues related to both the amount of water used and the potential impact on water quality. The largest single use of water in power generation is for cooling the low-pressure steam from the turbine. An alternative to the use of water for cooling is air. However, air-cooled systems (sometimes referred to as dry systems) can have associated capital-cost and energy-inefficiency penalties, particularly in retrofit applications.

Grant applications are sought to reduce or eliminate the need for water for cooling purposed including: (1) Novel heat-transfer media that is more efficient than air; (2) improved fill materials used in re-circulating (closed loop) wet cooling towers; (3) approaches to reducing evaporative loss from closed wet systems; (4) innovations to improve the efficiency of dry cooling systems, particularly for retrofit applications; and (5) novel, lowcost treatment technology to allow for the use of process water as boiler feed water.

6.0 Conversion of Coal-Derived Synthesis Gas to Fischer-Tropsch (F–T) Liquids

The conversion of coal to Fischer-Tropsch liquids can help supplement petroleum in satisfying our Nation's growing demand for clean transportation fuels, but additional scientific understanding of the entire process is needed to enable technology developers to improve system performance and economics. Historically, empirically-derived laboratory data has been used to develop Fischer-Tropsch reactor systems and to determine operating conditions. Catalysis has played a significant role in helping to establish a reasonable range of operation conditions that provide less residence time, higher product yield and selectivity, and lower energy consumption. However, neither the exact reaction mechanisms nor individual kinetic expressions are known for advanced, iron-based catalysts that are currently being developed for three-phase slurry reactor systems.

Grant applications are requested for projects that focus on deriving mechanistic and kinetic expressions for converting coal-derived synthesis gas to F–T liquids via iron-based catalysts in a three-phase regime that may include a range of reactants and operating parameters that would be reasonable for a commercial F–T system. Proposals may include the use of commercial F–T catalysts as a baseline for comparative evaluations.

UCR Innovative Concepts Phase–I Program

The goal of solicited research under the Innovative Concepts (IC) Phase–I Program is to develop unique approaches for addressing fossil energy-related issues. These approaches should represent significant departures from

existing approaches, not simply incremental improvements. The IC Phase–I Program seeks ''out-of-the-box'' thinking; therefore, well-developed ideas, past the conceptual stage, are not eligible for the Phase–I Program. Applications are invited from individual college/university researchers. Joint applications (as described under the Core Program) will also be accepted, although no additional funds are made available for joint versus individual applications. Unlike the Core Program, student participation in the IC Phase–I proposed research is strongly encouraged, however, not required. Funding for Phase–I grants will be limited to a total of $50K over a 12-month period.

In the twenty-first century, the challenges facing coal and the electric utility industry continue to grow. Environmental issues such as pollutant control, both criteria and trace pollutants, waste minimization, and the co-firing of coal with biomass, waste, or alternative fuels will remain important. The need for increased efficiency, improved reliability, and lower costs will be felt as an aging utility industry faces deregulation. Advanced power systems, such as a Vision 21 plant, and environmental systems will come into play as older plants are retired and utilities explore new ways to meet the growing demand for electricity.

Innovative research in the coal conversion and utilization areas will be required if coal is to continue to play a dominant role in the generation of electric power. Technical topics like the ones identified below are potential examples of research areas of interest, however, the areas identified were not intended to be all-encompassing. Therefore, it is specifically emphasized that other subjects for coal research would receive the same evaluation and consideration for support as the examples cited.

Innovative Concepts Phase–I Technical Topics

Smart Sensing and Advanced Artificially Intelligent Control Systems

The development of innovative concepts and techniques for smart sensing and advanced artificially intelligent control systems are needed to foster concurrent development efforts with advanced power generations technologies such as fuel cells, turbines, and gasification. Similar systems are also needed to deal with increasingly stringent emissions requirements (SO^2 and NO_X) for existing coal-fired power plants. The goal for new sensors and controls technology is to develop low cost, reliable, and accurate systems that permit real time monitoring and optimization of complex systems. For DOE's Vision 21 program, these advanced systems will support the production of power, chemicals, fuels, and/or steam with the highest efficiencies possible and near-zero emissions. The primary barriers for existing technologies are the harsh conditions that sensors may be exposed to combined with the need for extreme accuracy and fast response times. Incremental improvements of existing sensor and control technologies are not desired but rather revolutionary ideas that have the sound scientific basis to support significant advancements in this technology area.

Fundamental Study of Reaction Mechanism of Magnesium Silicates with Carbonic Acid and Other Solutions

The carbonation of naturally occurring magnesium silicates has shown promise as a method of achieving long-term carbon sequestration. It has been demonstrated that magnesium silicates such as serpentine and olivine can be reacted with CO2 to produce a highly stable solid magnesium carbonate material. This process is based upon the dissolution of the magnesium silicates in an aqueous carbonic acid solution containing chemical additives such as NaCl. The critical rate-limiting step in the carbonation process is currently believed to be the release or dissolution of the magnesium from the silicate into the solution.

Faster and less energy intensive pathways must be identified in order to develop an economically viable process based on mineral carbonation. By gaining a better understanding of the fundamental reaction mechanisms, new approaches could be devised that offered faster and more economical carbonation routes. Consequently, gaining a better understanding of this process is of interest to the USDOE. Skilled investigators having the capability to conduct well-planned experimental and theoretical investigations that can elucidate the detailed reaction path, quantify reaction barriers, and develop strategies to increase carbonation reaction rates are encouraged to apply.

Nitrogen/Carbon Dioxide Separation

Since the primary source of greenhouse gas emissions, primarily carbon dioxide, is combustion of fossil fuels such as coal or natural gas, options to reduce carbon dioxide emissions are being examined. In particular, inorganic membranes based on metals, ceramics or zeolites are suitable for the separation of such gases because they can sustain severe conditions such as high pressure, chemical corrosion, and high temperature. Approaches are needed whereby the membrane can be tailored to separate carbon dioxide from the nitrogen, the latter being the predominant component in the flue gas of a fossil fuel fired power plant. For example, the separation could be caused by dopants in the inorganic membrane that prefer to bond with carbon dioxide and facilitate its surface diffusion along the pore wall. Proposals are invited wherein factors such as concentration of dopant and pore diameter will be investigated, along with molecular simulations, in order to maximize the separation factor.

Heterogeneous Reburning

Recently, reburning with coal and coal-derived chars have been demonstrated to be an effective route for the reduction of nitrogen oxide emissions in boilers. Research is necessary to identify concepts for further reductions of nitrogen oxides and other detrimental emissions, such as carbon monoxide, through heterogeneous reburning.

One example of such research is research to develop in-furnace combustion NO_X reduction technologies that would reduce NO_X emissions below 0.15 lb/MMBtu or be utilized in conjunction with other low cost NO_X reduction technologies such as SNCR to achieve this objective while significantly reducing the overall cost of compliance when compared to SCR.

UCR Innovative Concepts Phase–II Program

The goal of the Phase–II Program, the principal R&D effort of the IC Program, is to solicit research that augments research previously funded through the Phase–I Program. Funding for Phase–II grants will be limited to a total of $200K over a 3-year period and student participation will be required. Only institutions receiving a Phase–I grant awarded in fiscal years 2000 and 2001 will be eligible to submit an application for continuation of their Phase–I projects. It's anticipated that at least 2–3 institutions submitting an application with approaches that appear sufficiently promising from the Phase–I efforts could receive a Phase–II award in 2002.

Issued in Morgantown, WV on November 9, 2001.

Randolph L. Kesling, Director,

Acquisition and Assistance Division.

[FR Doc. 01–29244 Filed 11–21–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Energy Technology Laboratory; Notice of Availability of a Financial Assistance Solicitation

AGENCY: National Energy Technology Laboratory, Department of Energy (DOE).

ACTION: Notice of availability of a financial assistance solicitation.

SUMMARY: Notice is hereby given of the intent to issue Financial Assistance Solicitation No. DE–PS26–02NT41423 entitled ''Black Liquor/Biomass Gasification Technology Support Research and Development.'' It is the intent of the National Energy Technology Laboratory (NETL), on behalf of the Office of Industrial Technologies (OIT) in the U.S. Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy, to solicit the submission of applications for black liquor/biomass gasification technology support research and development. The areas of interest are: TA–1 Fuels Chemistry; TA–1a Fuels Chemistry—Immediate Needs for Demonstration; TA–1b Fuels Chemistry—Optimization Needs for Sustainable Performance; TA–2 Containment, TA–3 Mill Integration—Steam, Power, Pulping, Causticizing; TA–3a Mill Integration—Steam, Power, Pulping Causticizing—Immediate Needs for Demonstration; TA–3b Mill Integration—Steam, Power, Pulping, Causticizing,—Optimization Needs for Sustainable Performance; TA—4 Process Control and Optimization; TA4a—Process Control and Optimization—Immediate Needs for Demonstration; TA–4b—Process Control and Optimization—Optimization Needs for Sustainable Performance; TA–5—Assurance and Education; TA–5a Assurance and Education—Immediate Needs for Demonstration; TA–5b Assurance and Education—Optimization Needs for Sustainable Performance; TA–6 Project Specific Field Support.

DATES: The solicitation will be available through the DOE/NETL's Internet address at *http://www.netl.doe.gov/business* and can be accessed on the ''Industry Interactive Procurement System'' (IIPS) webpage located at *http://e-center.doe.gov* on or around November 15, 2001.

ADDRESSES: NA.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah J. Boggs, MS IO7, U.S. Department of Energy, National Energy Technology Laboratory, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, WV 26507–0880, E-mail Address: *dboggs@netl.doe.gov,* Telephone Number: 304–285–4473.

SUPPLEMENTAL INFORMATION: Applied and/or bench-scale research and development support efforts are to be undertaken. These efforts are expected to be promising new concepts and optimization efforts in support of black liquor recovery and biomass gasification technologies to the point that they can be demonstrated in industrial applications, with primary interest in the demonstration projects that are underway. The scope of funded activities is to cover, applied research and development, applications engineering, and proof of concept at the laboratory-scale. Technical areas needed to be addressed include those that are of immediate needs for the demonstration projects and those that optimize existing systems/concepts to improve/sustain gasification performance. The Government anticipates 5–10 awards. Individual awards may range from $500,000–$1.5 million in Government cost-share. The DOE intends to award cooperative agreements, but reserves the right to award whatever instrument is considered to be in the Government's best interest. In accordance with EPAct, applicants are advised that this solicitation contains a recipient 20% cost share requirement for research and development projects and 50% cost share for demonstration or commercial application projects. This is a percent of the total award value, not as a percent of the Government's share. The duration of these projects is expected to range between 3–5 years.

Once released, the solicitation will be available for downloading from the IIPS Internet page. At this Internet site you will also be able to register with IIPS, enabling you to submit an application. If you need technical assistance in registering or for any other IIPS function, call the IIPS Help Desk at (800) 683–0751 or E-mail the Help Desk personnel at *IIPS—HelpDesk@e-center.doe.gov.* The solicitation will only be made available in IIPS, hard (paper) copies of the solicitation and related documents will not be made available.

Prospective applicants who would like to be notified as soon as the solicitation is available should subscribe to the Business Alert Mailing List at *http://www.netl.doe.gov/business.* Once you subscribe, you will receive an announcement by E-mail that the solicitation has been posted on IIPS. Telephone requests, written requests, E-mail requests, or facsimile requests for a copy of the solicitation package will not be accepted and/or honored. Applications must be prepared and submitted in accordance with the instructions and forms contained in the solicitation. The actual solicitation document will allow for requests for explanation and/or interpretation.

Issued in Morgantown, WV on November 9, 2001.

Randolph L. Kesling,

Director, Acquisition and Assistance Division.

[FR Doc. 01–29245 Filed 11–21–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Northeast Oregon Hatchery—Grande Ronde and Imnaha Spring Chinook Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of intent to prepare an environmental impact statement (EIS) and notice of floodplain and wetlands involvement.

SUMMARY: This notice announces BPA's intention to prepare an EIS on the development of additional supplementation facilities and modifications to existing facilities to support the mitigation of impacts to natural populations of spring chinook salmon in the Grande Ronde and Imnaha River basins. The U.S. Fish and Wildlife Service (USFWS), Department of Interior; and the U.S. Forest Service (USFS), Department of Agriculture, are cooperating agencies. The EIS will describe the proposed alternatives for fish trapping, rearing, and release facilities to help restore spring chinook salmon populations in the Imnaha River and Lostine River (a tributary in the Grande Ronde River basin) of Northeast Oregon. The planned facilities will modify and supplement existing facilities built for the Lower Snake River Compensation Plan (LSRCP), a program authorized by Congress in 1976 and administered by USFWS to compensate for spring, summer, and fall chinook salmon and steelhead losses caused by the construction and operation of four Federal dams on the lower Snake River. This action may involve floodplain and wetlands located in Wallowa and Union Counties, Oregon. In accordance with DOE regulations for compliance with floodplain and wetlands environmental review requirements, BPA will prepare a floodplain and wetlands assessment and would perform this proposed action so as to avoid or minimize potential

harm to or within the affected floodplain and wetlands. The assessment and a floodplain statement of findings will be included in the EIS being prepared for the proposed project in accordance with the National Environmental Policy Act (NEPA).

DATES: Written comments on the scope of the Draft EIS are due to the address below no later than January 31, 2002. Comments may also be made at EIS scoping meetings to be held at the locations below on January 15, 16, and 17, 2002.

ADDRESSES: Send comment letters and requests to be placed on the project mailing list to Communications, Bonneville Power Administration—KC–7, P.O. Box 12999, Portland, Oregon, 97212. The phone number of the Communications office is 503–230–3478 in Portland; toll-free 1–800–622–4519 outside of Portland. Comments may also be sent to the BPA Internet address: comment@bpa.gov, or faxed to: 503–230–3285.

EIS scoping meetings will be held at the Imnaha Christian Fellowship, 78782 Imnaha Highway, Imnaha, Oregon, at 7 p.m. on January 15, 2002; at the South Fork Grange, 131 Highway 82, Lostine, Oregon, at 7 p.m. on January 16, 2002; and at Eastern Oregon University, Hoke Hall, 1 University Boulevard (intersection of 7th Street and I Avenue), LaGrande, Oregon, at 7 p.m. on January 17, 2002.

FOR FURTHER INFORMATION CONTACT: Patricia Smith, Environmental Project Lead—KEC–4, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon, 97208–3621, phone number 503–230–7349, fax number 503–230–5699, e-mail prsmith@bpa.gov; or Jay Marcotte, Project Manager—KEWL–4, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon, 97208–3621, phone number 503–230–3943, fax number 503–230–3943, e-mail *jgmarcotte@bpa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Lookingglass Fish Hatchery was originally designed and constructed under the LSRCP program to produce two stocks of fish, the Imnaha stock for the Imnaha subbasin and a second stock for the Grande Ronde subbasin. Production of spring chinook salmon under this program began in the early 1980s. Beginning in the early 1990s, the fishery managers recognized that many natural populations in Northeast Oregon were at imminent risk of extirpation and immediate action was necessary. All natural spring chinook salmon populations in the Snake River, including the Imnaha and Grande Ronde Rivers, were listed by the National Marine Fisheries Service (NMFS) as threatened under the Endangered Species Act (ESA) in May 1992. In response to the listings, the States, Tribes, and USFWS developed plans to conserve Imnaha and Grande Ronde spring chinook salmon using captive broodstock and hatchery supplementation as the preferred artificial propagation approaches. These programs were designed to shift the emphasis of the LSRCP program from compensation to conservation and restoration. Plans in the mid-1990s to conserve four stocks under ESA permits issued by NMFS were implemented. Because the new programs did not increase numbers of fish to be produced at Lookingglass Fish Hatchery, an assumption was made that the existing facility, with minor modifications, would be sufficient to meet the needs.

Proposed Action

Recently, fishery managers determined that it is not possible to meet the entire program's needs at Lookingglass Fish Hatchery and that, without additional facilities, production must be cut from the conservation components of the program. Therefore, this project proposes to modify the existing Lookingglass Fish Hatchery and Imnaha satellite facility and build new facilities on the Lostine and Imnaha Rivers. A new incubation, rearing, and trapping facility is proposed for the Lostine River, a Grande Ronde basin tributary, and a new rearing facility is proposed for the Imnaha River. In addition, modifications are proposed to the Lookingglass Fish Hatchery on the Grande Ronde River and the Imnaha satellite facility on the Imnaha River. This project does not involve program issues or increases in the number of fish to be produced, but rather new and upgraded facilities that support an existing approved program and level of fish production. Potential exists for spanning or locating structures in the surrounding floodplains and activities may involve wetlands on those sites.

Process to Date

Based on similar site-specific projects, an initial decision was made to initiate an Environmental Assessment (EA). An EA Determination was signed on November 20, 2000, with the expectation that a Finding of No Significant Impact would be attained. However, the Imnaha portion of this project is located within the boundaries of the Hells Canyon National Recreation Area and the Imnaha Wild and Scenic River. Modifications to the existing Imnaha satellite facility and any new Imnaha facilities may involve construction in the Imnaha River that could create significant impacts. Therefore, it has been determined that the appropriate level of environmental coverage is an EIS.

This is a multi-party project involving Tribal governments, State agencies, and Federal agencies. The parties include the Nez Perce Tribe (NPT), the Confederated Tribes of the Umatilla Indian Reservation (CTUIR), Oregon Department of Fish and Wildlife (ODFW), USFS, USFWS, NMFS, and BPA. Scoping began during the EA process and will continue for at least 30 days after the filing of this notice of intent to prepare an EIS, gathering information on the extent of the action, range of alternatives, and the types of effects to be evaluated. NEPA and other environmental laws and regulatory requirements will be merged into an overall integrated process that ensures compliance with all Federal and State legal prerequisites. A review process in accordance with the specific requirements of each agency's NEPA regulations and manuals will allow for an integrated effort that provides a full disclosure.

Alternatives Proposed for Consideration

A reasonable range of alternatives for this project would include a proposed action that examines a combination of facility sites, new and existing with upgrades, that would reasonably accommodate the LSRCP biological criteria and program objectives. Connected, similar, and cumulative actions will be considered, along with a reasonable range of alternatives that could fulfill the purpose and need of the proposed action, including a no-action alternative. Mitigation measures will be considered, separate from features of the proposed action, that could avoid or substantially reduce the environmental consequences of the proposed action.

Public Participation and Identification of Environmental Issues

BPA has reinitiated scoping for this project, establishing a scoping period during which affected landowners, concerned citizens, special interest groups, local governments, and any other interested parties are invited to comment on the scope of the proposed EIS. Scoping will help BPA ensure that a full range of issues related to this proposal is addressed in the EIS, and also will identify significant or potentially significant impacts that may result from the proposed project. At

these informal meetings, NPT, CTUIR, ODFW, USFS, USFWS, and BPA will provide detailed information about the proposed facilities and modifications to existing facilities. Written information will also be available, and BPA staff will answer questions and accept oral and written comments. When completed, the Draft EIS will be circulated for review and comment, and BPA will hold public comment meetings for the Draft EIS. BPA will consider and respond in the Final EIS to comments received on the Draft EIS.

The proposed action and alternatives will be examined for environmental effects on the affected environment. The types of impacts that will be considered include foreseeable direct and indirect effects as well as past, present, and reasonably foreseeable future cumulative effects. Issues raised during the scoping process will be examined and addressed in the Draft EIS.

Maps and further information are available from BPA at the address above.

Issued in Portland, Oregon, on November 14, 2001.

Stephen J. Wright,

Acting Administrator and Chief Executive Officer.

[FR Doc. 01–29247 Filed 11–21–01; 8:45 am]

BILLING CODE 6450–01–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–415–000]

East Tennessee Natural Gas Company; Notice of Public Working Meetings

November 16, 2001.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will hold additional public working meetings to discuss the environmental impacts of the East Tennessee Natural Gas Company's (East Tennessee) Patriot Project in Tennessee, Virginia, and North Carolina.

The locations and times for these meetings are listed below.

Tuesday, November 27, 2001, 7:30–10 p.m. Carroll County High School Auditorium, 100 Cavs Lane, Hillsville, VA 24343, (540) 728–2165 or (540) 236–4455

Thursday, November 29, 2001, 7:30–10 p.m. Martinsville Middle School Auditorium, 201 Brown Street, Martinsville, VA 24112, (276) 634–5728

These public working meetings are designed to provide you with more information about the project, and an opportunity for you to discuss the project and alternatives with FERC staff. You may also submit written comments at the meeting.

On the dates of the meetings, we will also be conducting limited site visits of the project area, and on November 28, 2001, staff will conduct overflight of the project area. Anyone interested in participating in the site visits may contact the Commission's Office External Affairs at (201) 208–1088 for more details and must provide their own transportation.

David P. Boergers,

Secretary.

[FR Doc. 01–29237 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP96–128–012]

Eastern Shore Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

November 16, 2001.

Take notice that on November 6, 2001, Eastern Shore Natural Gas Company (Eastern Shore) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets with a proposed effective date of November 1, 2001:

First Revised Sheet No. 1
First Revised Sheet No. 9
Original Sheet No. 10

Eastern Shore states that the purpose of this filing is to provide the requisite information concerning the specific negotiated rate service agreement with PECO Energy Company (PECO). Such requisite information includes the exact legal name of the shipper, the negotiated rate and other applicable charges, the applicable rate schedule, the primary receipt and delivery points, contract quantity and a statement affirming that the negotiated rate service agreement does not deviate in any material aspect from the form of service agreement contained in Eastern Shore's FERC Gas Tariff.

Eastern Shore states that copies have been mailed to all customers and interested state commissions.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–29236 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP02–24–000]

PG&E Gas Transmission, Northwest Corporation; Notice of Application

November 16, 2001.

Take notice that on November 9, 2001, PG&E Gas Transmission, Northwest Corporation (PG&E) filed an application pursuant to Section 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations for a certificate of public convenience and necessity authorizing PG&E to construct a total of 53.6 miles of 42-inch diameter loop of its existing mainline system in Boundary County in Idaho, and Spokane, Whitman, and Walla Walla Counties in Washington, and Umatilla County in Oregon and to increse system compression by adding 19,500 ISO hp of compression at one existing compressor station (Station 14) in Klamath County, Oregon, all as more fully set forth in the application that is on file with the Commission and open to public inspection. Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

PG&E proposes this project to increase its system capacity by approximately

143,000 dekatherms per day (Dth/d) of annual pipeline capacity and by 20,000 Dth/d of winter only capacity. PG&E estimates that the cost of the facilities is estimated to be approximately $111.3 million, which it states will be financed using internally-generated funds. PG&E proposes to install the looping and compression facilities in order to provide the additional transportation service by November 2003 or sooner. PG&E requests Commission approval by December 31, 2002, at the latest, in order to complete the installation of the proposed facilities in time for the 2003/2004 winter heating season.

PG&E states that it held an open season in which it made capacity on its system available to interested shippers on a not unduly discriminatory basis. PG&E states that as a result it has executed binding, long term precedent agreements for a total of 143,000 Dth/d of annual service and 20,000 Dth/d of winter-only service for terms averaging 25.3 years with five shippers to serve new electric generation projects and other uses in the Pacific Northwest and California. This represents 100% of the proposed expansion capacity. PG&E states that these precedent agreements demonstrate that there is sufficient market demand for natural gas transportation service on PG&E's system to support this project.

Any questions regarding the application should be directed to John A. Roscher, Director, Rates and Regulatory Affairs, PG&E Gas Transmission, Northwest Corporation; 1400 SW Fifth Avenue, Suite 900; Portland, Oregon; 97201, (503) 833–4254.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before December 7, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. The preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–29239 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER02–303–000]

Williams Energy Marketing & Trading Company; Notice of Filing

November 15, 2001.

Take notice that on November 13, 2001, Williams Energy Marketing & Trading Company (Williams EM&T) tendered for filing with the Federal Energy Regulatory Commission (Commission) pursuant to section 205 of the Federal Power Act (FPA), 16 U.S.C. 824d (1994), and part 35 of the Commission's Regulations, 18 CFR part 35, revised pages to the Reliability Must-Run Service Agreements (RMR Agreements) between Williams EM&T and the California Independent System Operator Corporation (ISO) for certain RMR units located at the Alamitos and, Huntington Beach Generating Stations.

The purpose of the filing is to update Williams EM&T's existing RMR Agreements to reflect an extension of the two existing RMR Agreements and certain annual updates to Schedules A, B, D and J of the RMR Agreements. Copies of the filing were served upon the ISO and Southern California Edison Company.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before December 4, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on

file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–29240 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG02–26–000, et al.]

CPN 3rd Turbine, Inc., et al.; Electric Rate and Corporate Regulation Filings

November 15, 2001.

Take notice that the following filings have been made with the Commission:

1. CPN 3rd Turbine, Inc.

[Docket No. EG02–26–000]

Take notice that on November 9, 2001, CPN 3rd Turbine, Inc. (CPN) filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

CPN, a Delaware corporation, proposes to own and operate a 45 MW natural gas-fired, simple-cycle, combination turbine generator located at the John F. Kennedy International Airport. CPN will sell the output at wholesale to Calpine Energy Services, L.P., and other purchasers.

Comment date: December 6, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. FPL Energy Marcus Hook, L.P.

[Docket No. EG02–27–000]

Take notice that on November 13, 2001, FPL Energy Marcus Hook, L.P. (the Applicant), with its principal office at 700 Universe Boulevard, Juno Beach, FL 33408, filed with the Federal Energy Regulatory Commission (Commission), an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Applicant states that it is a Delaware limited partnership engaged directly and exclusively in the business of developing and operating an approximately 740 MW generating facility to be located in Marcus Hook, Pennsylvania. Electric energy produced by the facility will be sold at wholesale or at retail exclusively to foreign consumers.

Comment date: December 6, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Duke Energy Murray, LLC

[Docket No. EG02–28–000]

Take notice that on November 13, 2001, Duke Energy Murray, LLC (Duke Murray) filed with the Federal Energy Regulatory Commission (the Commission) for determination an application for exempt wholesale generator status pursuant to section 32 of the Public Utility Holding Company Act of 1935, as amended, and part 365 of the Commission's regulations.

Duke Murray is a Delaware limited liability company that will be engaged directly and exclusively in the business of owning and operating all or part of one or more eligible facilities to be located in Murray County, Georgia. The eligible facilities will consist of an approximately 1,240 MW natural gas-fired, combined cycle electric generation plant and related interconnection facilities. The output of the eligible facilities will be sold at wholesale.

Comment date: December 6, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Condon Wind Power, LLC

[Docket No. EG02–29–000]

Take notice that on November 13, 2001, Condon Wind Power, LLC (Condon Wind Power), whose sole member is SeaWest WindPower, Inc., located at 1455 Frazee Road, Ninth Floor, San Diego, California 92108, filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Condon Wind Power will construct, own or lease and operate a wind-powered generating facility located near Condon, Oregon (the Project). The Project, which is to be developed in two phases, will have a total maximum output of 49.8 MW. Phase I is expected to begin commercial operation no later than December 31, 2001; Phase II is expected to begin commercial operation on or about June 15, 2002. Condon Wind Power will be engaged directly and exclusively in the business of owning or leasing (or subleasing) and/or operating the Project and selling electric energy exclusively at wholesale within the meaning of section 32(a) of PUHCA.

Comment date: December 6, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

5. Duke Energy Murray, LLC

[Docket No. ER02–302–000]

Take notice that on November 13, 2001, Duke Energy Murray, LLC (Duke Murray) tendered for filing with the Federal Energy Regulatory Commission (Commission) pursuant to section 205 of the Federal Power Act its proposed FERC Electric Tariff No. 1.

Duke Murray seeks authority to sell energy and capacity, as well as ancillary services, at market-based rates, together with certain waivers and preapprovals. Duke Murray also seeks authority to sell, assign, or transfer transmission rights that it may acquire in the course of its marketing activities. Duke Murray seeks an effective date 60 days from the date of filing for its proposed rate schedules.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Southwest Power Pool, Inc.

[Docket No. ER02–304–000]

Take notice that on November 13, 2001, Southwest Power Pool, Inc. (SPP) submitted for filing with the Federal Energy Regulatory Commission (Commission) two service agreements for Firm Point-to-Point Transmission Service and Loss Compensation Service with Texas-NM Power Company (Transmission Customer).

SPP requests an effective date of November 8, 2001 for these service agreements. A copy of this filing was served on the Transmission Customer.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Condon Wind Power, LLC

[Docket No. ER02–305–000]

Take notice that on November 9, 2001, Condon Wind Power, LLC

(Condon Wind Power) applied to the Federal Energy Regulatory Commission (Commission) for acceptance of Condon Wind Power's Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electric energy and capacity at market-based rates; and the waiver of certain Commission regulations.

Comment date: November 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Southwest Power Pool, Inc.

[Docket No. ER02–306–000]

Take notice that on November 13, 2001, Southwest Power Pool, Inc. (SSP) submitted for filing with the Federal Energy Regulatory Commission (Commission) two executed service agreements for Firm Point-to-Point Transmission Service with Aquila Energy Marketing Corporation (Transmission Customer).

SPP requests and effective date of January 20, 2002 for these service agreements. A copy of this filing was served on the Transmission Customer.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. American Transmission Company LLC

[Docket No. ER02–307–000]

Take notice that on November 13, 2001, American Transmission Company LLC (ATCLLC) tendered for filing with the Federal Energy Regulatory Commission (Commission) Firm and Non-Firm Point-to-Point Service Agreements for El Paso Merchant Energy, L.P.

ATCLLC requests an effective date of October 31, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. RWE Trading Americas Inc.

[Docket No. ER02–308–000]

Take notice that on November 13, 2001, RWE Trading Americas Inc. (RWE Trading) filed with the Federal Energy Regulatory Commission (Commission) for acceptance of RWE Trading's FERC Electric Rate Schedule No. 1. In addition, RWE Trading requests a Commission order granting of certain blanket approvals, including the authority to sell electricity at market-based rates, and the waiver of certain Commission regulations. A January 9, 2002 effective date has been requested.

RWE Trading intends to engage in wholesale electric power and energy purchases and sales as a marketer. RWE Trading is not in the business of generating or transmitting electric power. RWE Trading is a wholly-owned subsidiary of RWE Trading GmbH of Essen, Germany, the European power marketing affiliate of RWE AG, Essen, Germany.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. MEP Clarksdale Power, LLC

[Docket No. ER02–309–000]

Take notice that on November 13, 2001, MEP Clarksdale Power, LLC (MEP Clarksdale), an indirect wholly owned subsidiary of Aquila, Inc., tendered for filing with the Federal Energy Regulatory Commission (Commission) a rate schedule to engage in sales at market-based rates. MEP Clarksdale included in its filing a proposed code of conduct.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Reliant Energy Desert Basin, LLC

[Docket No. ER02–310–000]

Take notice that on November 13, 2001, Reliant Energy Desert Basin, LLC (Reliant Energy Desert Basin) tendered for filing with the Federal Energy Regulatory Commission (Commission) a service agreement establishing Reliant Energy Services, Inc. (RES) as a customer under Reliant Energy Desert Basin's market-based rate tariff. Reliant Energy Desert Basin states that a copy of the filing was served on RES.

Reliant Energy Desert Basin requests an effective date of October 12, 2001 for the service agreement.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Southern Indiana Gas and Electric Company

[Docket No. ER02–311–000]

Take notice that on November 13, 2001, Southern Indiana Gas and Electric Company (SIGECO), tendered for filing with the Federal Energy Regulatory Commission (Commission) Agreements for Firm and Non-Firm Point-To-Point Transmission Service with Axia Energy, LP under Part II of SIGECO's Transmission Services Tariff, Docket No. 0A96–117–000, filed July 9, 1996. To date, no Service has been provided by SIGECO to Calpine Energy Services, L.P. pursuant to this Agreement.

SIGECO requests waiver of the 60-day prior notice requirement to allow the service agreements to become effective as of August 6, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Southern Indiana Gas and Electric Company

[Docket No. ER02–312–000]

Take notice that on November 13, 2001, Southern Indiana Gas and Electric Company (SIGECO) tendered for filing with the Federal Energy Regulatory Commission (Commission) Agreements for Firm and Non-Firm Point-To-Point Transmission Service with Calpine Energy services, L.P. under Part II of SIGECO's Transmission Services Tariff, Docket No. 0A96–117–000, filed July 9, 1996. To date, no Service has been provided by SIGECO to Calpine Energy Services, L.P. pursuant to this Agreement.

SIGECO requests waiver of the 60-day prior notice requirement to allow the service agreements to become effective as of July 13, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Southern Indiana Gas and Electric Company

[Docket No. ER02–313–000]

Take notice that on November 13, 2001, Southern Indiana Gas and Electric Company (SIGECO) tendered for filing with the Federal Energy Regulatory Commission (Commission) Agreements for Firm and Non-Firm Point-To-Point Transmission Service with Exelon Generation Company, LLC under Part II of SIGECO's Transmission Services Tariff, Docket No. 0A96–117–000, filed July 9, 1996. To date, no Service has been provided by SIGECO to Exelon Generation Company, LLC pursuant to this Agreement.

SIGECO requests waiver of the 60-day prior notice requirement to allow the service agreements to become effective as of August 6, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Southern Indiana Gas and Electric Company

[Docket No. ER02–314–000]

Take notice that on November 13, 2001, Southern Indiana Gas and Electric Company (SIGECO), tendered for filing with the Federal Energy Regulatory Commission (Commission) Agreements for Firm and Non-Firm Point-To-Point Transmission Service with Allegheny Energy Supply Company, LLC under Part II of SIGECO's Transmission Services Tariff, Docket No. 0A96–117–000, filed July 9, 1996. To date, no Service has been provided by SIGECO to Alleghney Energy Supply Company pursuant to this Agreement.

SIGECO requests waiver of the 60-day prior notice requirement to allow the service agreements to become effective as of March 19, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Southern Indiana Gas and Electric Company

[Docket No. ER02–315–000]

Take notice that on November 13, 2001, Southern Indiana Gas and Electric Company (SIGECO) tendered for filing with the Federal Energy Regulatory Commission (Commission) an Agreement for Firm Point-To-Point Transmission Service with SIGECO Wholesale Power Marketing under Part II of SIGECO's Transmission Services Tariff, Docket No. 0A96–117–000, filed July 9, 1996. To date, no Service has been provided by SIGECO to SIGECO Wholesale Power Marketing pursuant to this Agreement.

SIGECO requests waiver of the 60-day prior notice requirement to allow the service agreements to become effective as of March 2, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Xcel Energy Services, Inc.

[Docket No. ER02–316–000]

Take notice that on November 13, 2001, Xcel Energy Services, Inc. (XES), on behalf of Public Service Company of Colorado (Public Service), submitted for filing with the Federal Energy Regulatory Commission (Commission) a Master Power Purchase and Sale Agreement between Public Service and Wabash Valley Power Association, Inc. (Wabash), which is in accordance with Public Service's Rate Schedule for Market-Based Power Sales (Public Service FERC Electric Tariff, First Revised Volume No. 6).

XES requests that this agreement become effective on November 13, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Sierra Pacific Power Company

[Docket No. ER02–317–000]

Take notice that on November 13, 2001, Sierra Pacific Power Company tendered for filing with the Federal Energy Regulatory Commission (Commission) pursuant to Section 205 of the Federal Power Act, an executed Modification No. 1 to Network Integration Transmission Service Agreement (Modification to Service Agreement) between Sierra Pacific Power Company and the Truckee Donner Public Utility District. The Network Integration Transmission Service Agreement was filed in compliance with Section 29.5 of the Sierra Pacific Resources Operating Companies Open Access Transmission Tariff and accepted for filing effective September 15, 1999. The Modification Agreement is being filed at the request of the Truckee Donner Public Utility District.

Sierra has requested that the Commission accept the Modification to Service Agreement and permit service in accordance therewith effective October 1, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Sierra Pacific Power Company

[Docket No. ER02–318–000]

Take notice that on November 13, 2001, Sierra Pacific Power Company tendered for filing with the Federal Energy Regulatory Commission (Commission) pursuant to section 205 of the Federal Power Act, an executed Modification No. 1 to Network Integration Transmission Service Agreement (Modification to Service Agreement) between Sierra Pacific Power Company and the City of Fallon. The Network Integration Transmission Service Agreement was filed in compliance with section 29.5 of the Sierra Pacific Resources Operating Companies Open Access Transmission Tariff and accepted for filing effective May 8, 2000.

The Modification Agreement is being filed at the request of the City of Fallon. Sierra has requested that the Commission accept the Modification Agreement and permit service in accordance therewith effective September 1, 2001.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. CinCap VII, LLC

[Docket No. ER02–319–000]

Take notice that on November 13, 2001, CinCap VII, LLC tendered for filing with the Federal Energy Regulatory Commission (Commission) a notice of change in status and amendments to its market-based rate tariff and code of conduct to reflect certain changes in its ownership.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. The Montana Power Company

[Docket No. ER02–321–000]

Take notice that on November 13, 2001, Montana Power Company (Montana Power) filed with the Federal Energy Regulatory Commission (Commission) pursuant to Section 205 of the Federal Power Act supplements to Rate Schedule FERC No. 174, the General Transfer Agreement between Montana Power and the Bonneville Power Administration (BPA). Montana Power states that the supplements are being filed to update Transfer Charges for service rendered by Montana Power to BPA based on changes in certain transmission rates charged by BPA. Montana Power has proposed to make each of the supplements effective in accordance with their terms.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. CinCap Madison, LLC

[Docket No. ER02–322–000 and ER00–1784–002]

Take notice that on November 13, 2001, CinCap Madison, LLC tendered for filing with the Federal Energy Regulatory Commission (Commission) a notice of change in status and amendments to its market-based rate tariff and code of conduct to reflect certain changes in its ownership.

Comment date: December 4, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–29201 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2077–016—NH/VT]

USGenNE; Notice of Availability of Environmental Assessment

November 16, 2001.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for a new license for the Fifteen Mile Falls Hydroelectric Project located on the Connecticut River, in Grafton County, New Hampshire and Caledonia County, Vermont, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission's staff has analyzed the potential environmental effects of the project and has concluded that approval of the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, Room 2-A, of the Commission's offices at 888 First Street, NE., Washington, DC 20426. The EA may also be viewed on the web at *http://www.ferc.fed.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions. Please call (202) 208–2222 for assistance.

Any comments should be filed within 30 days from the date of this notice and should be addressed to David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1–A, Washington, DC 20426. Please affix ''Fifteen Mile Falls Hydroelectric Project No. 2077–016'' to all comments. For further information, contact William Guey-Lee at (202) 219–2808. Comments may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

David P. Boergers,

Secretary.

[FR Doc. 01–29242 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP02–1–000]

Southern Natural Gas Company; Notice of Intent To Prepare an Environmental Assessment for the Proposed South System Expansion II Project and Request for Comments on Environmental Issues

November 16, 2001.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the South System Expansion II Project involving construction and operation of facilities by Southern Natural Gas Company (Southern) in St. Tammany Parish, Louisiana; Clarke, Lauderdale, and Jefferson Davis Counties, Mississippi; Sumter, Marengo, Hale, Perry, Autauga, Elmore, Tallapoosa, and Lee Counties, Alabama; and Harris, Talbot, Monroe, Bibb, Jones, Baldwin, Washington, Jefferson, Richmond, Upson, Effingham, and Chatham Counties, Georgia.[1] These facilities consist of about 123.3 miles of 36-, 30-, and 24-inch-diameter pipeline, modifications to 9 existing compressor stations, construction of a new compressor station on the site of a previously abandoned compressor station, taps, and a meter station. The EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' was attached to the project notice Southern provided to landowners. This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet website (www.ferc.fed.us).

Summary of the Proposed Project

Southern is proposing the South System Expansion II Project to expand its existing mainline system and increase capacity of its facilities in Louisiana, Mississippi, Alabama, and Georgia to supply increased quantities of gas to existing local distribution customers due to population growth in the region and the increasing demand for energy resources. The expansion of its facilities would enable Southern to provide for additional firm transportation capacity to serve eight shippers. This project would allow Southern to deliver 359,891 thousand cubic feet per day (Mcfd) of gas to these shippers.

Southern proposes to construct, install, and operate certain pipeline loops, compression, a meter station, and other appurtenances, in two phases. Phase I would consist of the facilities necessary to provide about 320,714 Mcfd of gas, and Phase II would consist of the facilities necessary to provide the remaining 39,177 Mcfd of gas.

Southern proposes to construct and operate the following facilities:

Phase I Facilities

- 36-inch South Main 3rd Loop Line (Loop 1): about 13.9 miles of 36-inch-diameter pipeline loop[2] of its South Main Line System from milepost (MP) 75.9 in Clarke County, Mississippi to MP 89.8 in Lauderdale County, Mississippi;
- 36-inch South Main 3rd Loop Line (Loop 2): about 9.6 miles of 36-inch-diameter pipeline loop of its South Main Line System from MP 115.7 in Sumter County, Alabama to MP 125.3 in Marengo County, Alabama;
- 36-inch South Main 4th Loop Line (Loop 3): about 11.0 miles of 36-inch-diameter pipeline loop of its South

[1] Southern's application was filed with the Commission on October 1, 2001, under Section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] A loop is a segment of pipeline that is installed adjacent to an existing pipeline and connected to it on both ends. The loop allows more gas to be moved through the pipeline system.

Main Line System from MP 138.9 to MP 149.9 in Hale County, Alabama;

• 30-inch South Main 3rd Loop Line (Loop 4): about 3.4 miles of 30-inch-diameter pipeline loop of its South Main Line System from MP 164.5 to MP 167.9 in Perry County, Alabama;

• 36-inch South Main 3rd Loop Line (Loop 5): about 7.9 miles of 36-inch-diameter pipeline loop of its South Main Line System from MP 197.9 to MP 205.8 in Autauga County, Alabama;

• 30-inch South Main 4th Loop Line (Loop 6): about 16.7 miles of 30-inch-diameter pipeline loop of its South Main Line System from MP 233.3 in Elmore County, Alabama to MP 250.0 in Tallapoosa County, Alabama;

• 30-inch South Main 3rd Loop Line (Loop 7): about 5.7 miles of 30-inch-diameter pipeline loop of its South Main Line System from MP 278.1 to MP 283.8 in Lee County, Alabama;

• 36-inch South Main 3rd Loop Line (Loop 8): about 16.6 miles of 36-inch-diameter pipeline loop of its South Main Line System from MP 311.6 in Harris County, Georgia to MP 328.2 in Talbot County, Georgia;

• 30-inch South Main 2nd Loop Line (Loop 9): about 9.5 miles of 30-inch-diameter pipeline loop of its South Main Line System from MP 362.7 to MP 372.2 in Monroe County, Georgia;

• 30-inch South Main 3rd Loop Line (Loop 10): about 7.6 miles of 30-inch diameter pipeline loop of its South Main Line system from MP 380.6 in Bibb County, Georgia to MP 388.2 in Jones County, Georgia;

• 24-inch South Main 2nd Loop Line (Loop 12): about 12.6 miles of 24-inch-diameter pipeline loop of its South Main Line System from MP 465.0 in Jefferson County, Georgia to MP 477.6 in Richmond County, Georgia; and

• One new meter station (Port Wentworth-SCANA Meter Station) at about MP 104.6 on its 20-inch-diameter Wrens-Savannah 2nd Loop Line in Chatham County, Georgia.

Southern also proposes to install compression and make other modifications at the following compressor stations:

• Add one 12,000 horsepower (hp) centrifugal compressor at the LaCombe Compressor Station in St. Tammany Parish, Louisiana. This would be a new compressor station built on an existing site where the original compressor station was previously dismantled;

• Rewheel compression on one existing unit at the Gwinville Compressor Station in Jefferson Davis County, Mississippi;

• Add one 6,000 hp high-speed engine driven reciprocating compressor at the Enterprise Compressor Station in Clarke County, Mississippi;

• Add one 15,000 hp centrifugal compressor and the removal of a 5,880 hp unit at the Gallion Compressor Station in Hale County, Alabama;

• Add one 15,000 hp centrifugal compressor, the installation of unloaders on one existing unit, and the removal of a 5,400 hp unit at the Elmore Compressor Station in Elmore County, Alabama;

• Add one 6,000 hp reciprocating compressor at the Ellerslie Compressor Station in Harris County, Georgia;

• Add one 4,000 hp reciprocating compressor at the Ocmulgee Compressor Station in Bibb County, Georgia;

• Add two 3,550 hp high-speed engine driven reciprocating compressors at the Hall Gate Compressor Station in Baldwin County, Georgia; and

• Add two 3,550 hp high-speed engine driven reciprocating compressors at the Wrens Compressor Station in Jefferson County, Georgia.

Southern also proposes to construct two dual 12-inch taps at about MP 94.5 on its existing 20-inch and 14-inch Wrens-Savannah Lines in Effingham County, Georgia; two dual 12-inch taps at about MP 491.2 on its existing 16-inch South Main and Loop Lines in Richmond County, Georgia; and two 8-inch taps at about MP 104.6 on its existing 20-inch Wrens Savannah Lines in Chatham County, Georgia.

Further, Southern proposes to remove previously abandoned pipe from its existing right-of-way at several locations. On Loop 5, in Autauga County, Alabama, Southern proposes to remove a total of about 6.3 miles of 12-inch pipe between MP 197.9 and MP 200.0, and MP 201.6 and MP 205.8 of its existing South Main Line System. On Loop 6, in Elmore and Tallapoosa Counties, Alabama, Southern proposes to remove a total of about 1.4 miles of 12-inch pipe between MP 233.3 and MP 233.9; MP 241.2 and MP 241.5; and MP 246.7 and 247.2 of its existing South Main Line System.

Phase II Facilities

• 30-inch South Main 2nd Loop Line (Loop 9): about 4.0 miles of 30-inch-diameter pipeline loop of its South Main Line system from MP 372.2 to MP 376.2 in Monroe County, Georgia; and

• 30-inch South Main 3rd Loop Line (Loop 11): about 4.8 miles of 30-inch-diameter pipeline loop of its South Main Line System from MP 420.2 in Baldwin County, Georgia to MP 425.0 in Washington County, Georgia.

Southern also proposes to install compression and make other modifications at the following compressor station:

• Add one 4,730 hp high-speed engine driven reciprocating compressor at the Thomaston Compressor Station in Upson County, Georgia.

The general location of Southern's proposed facilities is shown on the map attached as appendix 1.[3]

Land Requirements for Construction

Construction of Southern's proposed facilities would require about 1,488 acres of land, including construction right-of-way for the loops, taps, and the meter station; and extra work areas needed for pipe storage yards, staging areas, and warehouse sites. The majority of the loops would be constructed directly adjacent to Southern's existing rights-of-way. For the construction of the 30- and 36-inch-diameter loop segments, Southern proposes to use a 95-foot-wide construction right-of-way, which includes a 25-to 55-foot overlap of the existing right-of-way for workspace and temporary spoil storage. For the installation of the 24-inch-diameter pipeline on Loop 12, Southern proposes to use a 75-foot-wide construction right-of-way, which includes a 60-foot overlap of the existing right-of-way, with 15-feet of new temporary construction right-of-way to be cleared. Because of the use of Southern's existing right-of-way for construction, Southern indicates that only about 107 acres would be maintained as new permanent right-of-way.

The upgrades and modifications to the compressor stations would be performed within the existing Southern facilities, and would not require the clearing of additional land.

Construction access to Southern's project generally would be via the construction right-of-way and existing road network. Southern has identified 135 existing private access roads necessary for the construction of its project.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and

[3] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies are available on the Commission's website at the ''RIMS'' link or from the Commission's Public Reference and Files Maintenance Branch, 888 First Street, NE, Room 2A, Washington, DC 20426, or call (202) 208–1371. For instructions on connecting to RIMS refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

Necessity. NEPA also requires us [4] to discover and address concerns the public may have about proposals. We call this ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils
- Water resources and wetlands
- Vegetation and wildlife reliability and safety
- Threatened and endangered
- Cultural resources
- Land use
- Air quality and noise species

We will evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the public participation section beginning on page 8.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by Southern. This preliminary list of issues may be changed based on your comments and our analysis.

- Water Resources and Wetlands

—Crossing 91 perennial waterbodies.

—Crossing 29 wetlands, including 42.8 acres of forested wetlands.

- Vegetation

—About 354.5 acres of upland forest to be cleared.

—Potential impact on 7 Federally-listed threatened and endangered plant species.

- Threatened and Endangered Species

—Potential impact on 6 Federally-listed bird species.

—Potential impact on 3 Federally-listed reptile species.

—Potential impact on 3 Federally-listed fish species.

—Potential impact on 13 Federally-listed invertebrate species.

—Potential impact on 2 Federally-listed amphibian species.

- Soils

—About 33.6 miles of the pipeline right-of-way have soils with a high susceptibility to erosion.

—Crossing about 36.0 miles of prime farmland.

- Land Use

—Impact on 41 residences located within 50 feet of the construction work area.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative locations or routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your letter to: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First St., N.E., Room 1A, Washington, DC 20426;
- Label one copy of the comments for the attention of Gas 1, PJ–11.1;
- Reference Docket No. CP02–1–000; and
- Mail your comments so that they will be received in Washington, DC on or before December 17, 2001.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

If you do not want to send comments at this time but still want to remain on our mailing list, please return the Information Request (appendix 3). If you do not return the Information Request, you will be removed from the environmental mailing list.

Due to current events, we cannot guarantee that we will receive mail on a timely basis from the U.S. Postal Service, and we do not know how long this situation will continue. However, we continue to receive filings from private mail delivery services, including messenger services in a reliable manner. The Commission encourages electronic filing of any comments or interventions or protests to this proceeding. We will include all comments that we receive within a reasonable time frame in our environmental analysis of this project.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor.'' Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide 14 copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (see appendix 2). Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance).

Similarly, the ''CIPS'' link on the FERC Internet website provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings. From the FERC Internet website, click on the ''CIPS'' link, select ''Docket #'' from the

[4] ''We'', ''us'', and ''our'', refer to the environmental staff of the Office of Energy Projects (OEP).

CIPS menu, and follow the instructions. For assistance with access to CIPS, the CIPS helpline can be reached at (202) 208–2474.

David P. Boergers,

Secretary.

[FR Doc. 01–29238 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Tendered for Filing With the Commission, Establishing Procedures for Relicensing, and a Deadline for Submission of Final Amendments

November 16, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* P–2000–036.

c. *Date Filed:* October 31, 2001.

d. *Applicant:* Power Authority of the State of New York.

e. *Name of Project:* St. Lawrence-FDR Power Project.

f. *Location:* Located on the St. Lawrence River near Massena, in St. Lawrence County, New York. There are no Federal lands located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791 (a)–825(r).

h. *Applicant Contact:* Mr. Joseph J. Seymour, Chairman and Chief Executive Officer, Power Authority of the State of New York, 30 South Pearl Street, Albany, NY 12207–3425, (518) 433–6751.

Mr. John J. Suloway, Director, Licensing Division, Power Authority of the State of New York, 123 Main Street, White Plains, NY 10601–3170, (914) 287–3971.

i. *FERC Contact:* Ed Lee, (202) 219–2809 or E-Mail *ed.lee@ferc.fed.us.*

j. The existing St. Lawrence-FDR Power Project is part of the International St. Lawrence Power Project which spans the international portion of the St. Lawrence River and consists of two power developments: (1) the Robert H. Saunders Generating Station and (2) St. Lawrence-FDR Power Project. The Power Authority of the State of New York operates the St. Lawrence-FDR Power Project and the Ontario Power Generation operates the Robert H. Saunders Generating Station (located in Canada and not subject to the jurisdiction of the Commission).

The St. Lawrence-FDR Power Project facilities include (a) All or portions of four dams (Robert Moses Power Dam, Long Sault Dam, Massena Intake, and the U.S. portion of the Iroquois Dam), (b) generating facilities, (c) the U.S. portion of a reservoir (Lake St. Lawrence), (d) seven dikes, and (e) appurtenant facilities. The project has a total installed capacity of 912,000-kW and an average annual generation of about 6,650,000 megawatt hours. All generated power is utilized within the applicant's electric utility system.

k. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2–A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on *http://www.ferc.fed.us/online/rims.htm* (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

l. Procedural schedule and final amendments: The application will be processed according to the following milestones, some of which may be combined to expedite processing:

Notice of application has been accepted for filing
Notice soliciting final terms and conditions
Notice of the availability of the draft NEPA document
Notice of the availability of the final NEPA document
Order issuing the Commission's decision on the application

Final amendments to the application must be filed with the Commission no later than 45 days from the issuance date of the notice soliciting final terms and conditions.

David P. Boergers,

Secretary.

[FR Doc. 01–29241 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Non-Project Use of Project Lands and Waters and Soliciting Comments, Motions To Intervene, and Protests

November 16, 2001.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Project Use of Project Lands and Waters.

b. *Project No:* 2232–431.

c. *Date Filed:* October 26, 2001.

d. *Applicant:* Duke Energy Corporation.

e. *Name of Project:* Catawba-Wateree Hydroelectric Project.

f. *Location:* On Lake Norman at the Astoria Subdivision, in Catawba County, North Carolina. The project does not utilize federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. § 791(a)–825(r).

h. *Applicant Contact:* Mr. E.M. Oakley, Duke Energy Corporation, P.O. Box 1006 (EC12Y), Charlotte, NC 28201–1006. Phone: (704) 382–5778.

i. *FERC Contact:* Any questions on this notice should be addressed to Brian Romanek at (202) 219–3076, or e-mail address: brian.romanek@ferc.fed.us.

j. *Deadline for filing comments and motions:* December 26, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Please include the project number (2232–431) on any comments or motions filed.

k. *Description of Proposal:* Duke Energy Corporation proposes to lease to Bridgewater IV, LLC. one parcel of land underlying the project reservoir (a total of 0.577 acres) for a proposed commercial residential marina. The proposed lease area would accommodate 2 cluster boat docks and provide access to the reservoir for residents of the Astoria Subdivision. The proposed docks would accommodate 20 boats. No dredging is proposed.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at http://www.ferc.gov using the ''RIMS'' link, select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance).

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will

consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–29243 Filed 11–21–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Floodplain/Wetland Involvement at the Supply Creek Crossing for the Granby Pumping Plant-Marys Lake 69-Kilovolt Transmission Line, Grand County, Colorado

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of Involvement.

SUMMARY: Western Area Power Administration (Western), a power marketing agency of the U.S. Department of Energy (DOE), is the lead Federal agency for a proposal to reroute a 0.8 mile section of the Granby Pumping Plant-Marys Lake 69-kilovolt (kV) transmission line, located in Grand County, Colorado, approximately 10 miles north of the Town of Granby. Western plans to remove eight wood-pole H-frame structures from the existing right-of-way and relocate them farther to the west, a distance ranging from a few hundred feet to approximately 1,000 feet. All the proposed work will likely occur within a 100-year floodplain of Supply Creek. Both the existing transmission line and the proposed reroute cross a wetland associated with Supply Creek, as well as an irrigated meadow. The landowner has requested that Western relocate this section of line to facilitate his ongoing ranching operations. Access to this section of transmission line for maintenance is difficult due to hay meadow irrigation and naturally occurring wet conditions. Relocation of the line will reduce the number of transmission line structures presently located within the wetland area. In accordance with the DOE's Floodplain/Wetland Review Requirements (10 CFR 1022), Western will prepare a floodplain/wetland assessment and will perform the proposed actions in a manner so as to avoid or minimize potential harm to or within the affected floodplain/wetland.

DATES: Comments on the proposed floodplain/wetland action are due to the address below no later than December 10, 2001.

ADDRESSES: Comments should be addressed to Mr. Jim Hartman, Environmental Manager, Rocky Mountain Region, Western Area Power Administration, PO Box 3700, Loveland, CO, 80539–3003, fax (970) 461–7213, email *hartman@wapa.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Rodney Jones, Environmental Specialist, Rocky Mountain Customer Service Region, Western Area Power Administration, PO Box 3700, Loveland, CO 80539–3003, telephone (970) 461–7371, email *rjones@wapa.gov.*

SUPPLEMENTARY INFORMATION: The proposal to relocate a 0.8 mile section of the Granby Pumping Plant-Marys Lake 69-kV transmission line will involve construction activities within a floodplain and a wetland, including removal of eight existing wood pole H-frame transmission line structures and the installation of eight similar structures within a new relocated right-of-way. The structures located at either side of the relocation may be modified, or reconstructed, at the same location. Some construction activities would take place during the winter months when the ground is frozen to facilitate access in the extremely wet areas. The floodplain/wetland assessment will examine the proposed construction activities. The Supply Creek crossing is located in Grand County, Colorado in T.3 N., R. 76 W., sections 11 and 14. Maps and further information are available from the Western contact above.

Dated: November 8, 2001.

Michael S. Hacskaylo,

Administrator.

[FR Doc. 01–29246 Filed 11–21–01; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7107–1]

Access to Confidential Business Information by MacFadden & Associates, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of access to data and request for comments.

SUMMARY: EPA will authorize its contractor, MacFadden & Associates, Inc. (MAI) to access confidential business information (CBI) which has been submitted to EPA under the authority of all sections of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended. EPA has issued regulations that outline business confidentiality provisions for the Agency and require all EPA Offices that receive information designated by the submitter as CBI to abide by these provisions. MAI will provide support to the Office of Solid Waste (OSW) in operating the RCRA CBI Center (CBIC), a secure storage area that contains all records/documents that are received by OSW with a claim of business confidentiality.

DATES: Access to confidential data submitted to EPA will occur no sooner than December 3, 2001.

ADDRESSES: Comments should be sent to Regina Magbie, Document Control Officer, Office of Solid Waste (5305W), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Comments should be identified as ''Access to Confidential Data.''

FOR FURTHER INFORMATION CONTACT: Regina Magbie, Document Control Officer, Office of Solid Waste (5305W), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, 703–308–7909.

SUPPLEMENTARY INFORMATION:

1. Access to Confidential Business Information

Under EPA Contract No. GS–35F–0599J, MAI will assist the Information Management Branch, within the Communications, Information, and Resources Management Division, of the Office of Solid Waste (OSW) in operating the RCRA Confidential Business Information Center (CBIC). OSW collects data from industry to support the RCRA hazardous waste regulatory program. Some of the data collected from industry are claimed by industry to contain trade secrets or CBI. In accordance with the provisions of 40 CFR part 2, subpart B, OSW has established policies and procedures for handling information collected from industry, under the authority of RCRA, including RCRA Confidential Business Information Security Manuals. MAI shall protect from unauthorized disclosure all information designated as confidential and shall abide by all RCRA CBI requirements, including procedures outlined in the RCRA CBI Security Manual. MAI will also provide data base management support to the RCRA CBIC document tracking system.

The U.S. Environmental Protection Agency has issued regulations (40 CFR part 2, subpart B) that outlines business confidentiality provisions for the Agency and require all EPA Offices that receive information designated by the submitter as CBI to abide by these provisions. MAI will be authorized to have access to RCRA CBI under the EPA ''Contractor Requirements for the Control and Security of RCRA Confidential Business Information Security Manual.''

EPA is issuing this notice to inform all submitters of information under all sections of RCRA that EPA will provide HAZMED access to the CBI records located in the RCRA CBIC. Access to RCRA CBI under this contract will take place at EPA Headquarters only. Contractor personnel will be required to sign non-disclosure agreements and will be briefed on appropriate security procedures before they are permitted access to confidential information.

Dated: November 9, 2001.

Elizabeth A. Cotsworth,

Director, Office of Solid Waste.

[FR Doc. 01–29273 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6623–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated May 18, 2001 (97 FR 27647).

Draft EISs

ERP No. D–AFS–J65353–MT Rating EC2, Threemile Stewardship Project, Proposed Short-Term and Long-Term Vegetation and Road Management Activities, Ashland Ranger District, Custer National Forest, Powder and Rosebud Counties, MT.

Summary: EPA expressed environmental concerns and requested more detailed descriptions of alternatives, treatment types, road construction and reconstruction and further explanation of how environmental or ecological considerations will be integrated into the stewardship contracting and oversight. EPA recommended improvements in the air quality impact analysis for prescribed fire, and Alternative 4 which may provide greater watershed benefits.

ERP No. D–DOE–G06012–00 Rating EC2, Technical Area 18 (TA–18) Relocation of Capabilities and Materials at the Los Almos National Laboratory (LANL), Operational Activities Involve Research in and the Design, Development, Construction, and Application of Experiments on Nuclear Criticality, NM, NV and ID.

Summary: EPA expressed environmental concerns and asked for additional information and discussion in the FEIS on accident history and on weapons development activities at the sites under consideration.

ERP No. D–FAA–F51048–IL Rating LO, South Suburban Airport, Proposed Site Approval and Land Acquisition, For Future Air Carrier Airport, Will and Kankakee Counties, IL.

Summary: EPA had no environmental objections to the project as proposed.

ERP No. D–NOA–F39039–MI Rating LO, Indiana Lake Michigan Coastal Program Document, Federal Approval and Implementation, Coastal Zone Management, Lake, Porter and LaPorte Counties, MI.

Summary: EPA had no environmental objections to the program and DEIS which are positive steps in the long-term management of southern Lake Michigan's coastal resources. EPA encouraged NOAA to emphasize proactive management responses in the Coastal Program to water quality, control of invasive species and public health threats.

Final EISs

ERP No. F–AFS–G36152–NM Santa Fe National Forest, Santa Fe Municipal Watershed Project, Servere Crown Fire Reduction and Sustainable Forest and Watershed Conditions Restoration, Implementation, Pecos Wilderness to Cochitti Lake, Santa Fe National Forest, Santa Fe County, NM.

Summary: EPA expressed lack of environmental objections on the FEIS.

ERP No. F–BLM–K39058–CA Cadiz Groundwater Storage and Dry-Year Supply Program, Construction and Operation, Amendment of the California Desert Conservation Area (CDCA) Plan, Issuance of Right-of-Way Grants and Permits, San Bernardino County, CA.

Summary: EPA expressed environmental concerns that the project could result in long-term adverse impacts to groundwater, springs and seeps if monitoring and mitigation measures are not properly applied. Because we lack important baseline data, it will be critical to continually monitor impacts and refine models and management strategies. EPA recommended an independent third party review impact assessments be made by the Metropolitan Water District and the Technical Review Panel.

ERP No. F–NPS–K61153–CA Alcatraz Island Historic Preservation and Safety Construction Program, Protection and Implementation, San Francisco County, CA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. FS–JUS–A82111–00 Cannabis Eradication in the Contiguous United States and Hawaii, Updated Information concerning New Scientific Data on Herbicidal Eradication.

Summary: EPA review of the Final SEIS concludes that it adequately addresses EPA's environmental concerns expressed on the Draft SEIS.

ERP No. FS–UMC–K11067–00 Yuma Training Range Complex Management, Operation and Development, Marine Corps Air Station Yuma, Goldwater Range, Yuma and La Paz Cos., AZ and Chocolate Mountain Range, Imperial and Riverside Counties, CA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F1–AFS–J65250–CO Forest Development Trail (FDT) 1135 (Arapho Ridge Trail), Forest Development Road (FDR) 711.1 and FDR 711.1A Motorized or Non-Motorized Determination and Trailhead Parking Areas Creation at both ends of the Trail, Routt National Forest, Jackson County, CO.

Summary: No formal comment letter was sent to the preparing agency.

Dated: November 20, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–29274 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6623–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *www.epa.gov/oeca/ofa.*

Weekly receipt of Environmental Impact Statements filed November 12, 2001 through November 16, 2001 pursuant to 40 CFR 1506.9.

EIS No. 010433, Final EIS, AFS, CO, Nucla-Telluride Transmission Line Project, Permit Approval and Funding for Construction and Operation of a 115 kV Transmission Line between the Nucla Substation in Montrose County and either the Telluride or Sunshine Substations in San Miguel County, CO, *Wait Period Ends:* December 24, 2001, *Contact:* Steve Wells (970) 327–4261.

EIS No. 010434, Draft EIS, COE, ID, WA, McNary Reservoir and Lower Snake River Reservoirs, To Maintain the Authorized Navigation Channel, Dredged Material Management Plan (DMMP), Walla Walla District, Lower Snake River and Columbia River, ID and WA, *Comment Period Ends:* January 07, 2002, *Contact:* Jack Sand (509) 527–7287.

EIS No. 010435, Final EIS, COE, LA, West Bay Sediment Diversion Channel Project, Construction, Funding, Plaquemines Parish, LA, *Wait Period Ends:* December 24, 2001, *Contact:* Sean P. Mickal (504) 862–2319.

EIS No. 010436, Final EIS, FRC, MA, CT, Phase III/Hubline Project, Construction and Operation a Natural Gas Pipeline, Maritimes and Northeast Pipeline (Docket No. CPO1–4–000), Algonquin Gas Transmission (Docket No. CP01–5–000) and Texas Eastern Transmission (Docket No. CP01–8–000), MA and CT, *Wait Period Ends:* December 24, 2001, *Contact:* David P. Boergers (202) 208–1371.

EIS No. 010437, Final EIS, AFS, OR, Anthony Lakes Mountain Resort Master Development Plan, Upgrading and Additional Development, Approval, Baker Ranger District, Wallowa-Whitman National Forest, Grant, Union and Baker Counties, OR, *Wait Period Ends:* December 24, 2001, *Contact:* Charles L. Ernst (541) 523–1901.

EIS No. 010438, Final EIS, FHW, IL, Fox River Bridge Crossings, To Construct up to Five-Bridges across the Fox River, NPDES Permit, COE Section 10 and 404 Permits, Kane County, IL, *Wait Period Ends:* December 24, 2001, *Contact:* Norman R. Stoner (217) 492–4640.

EIS No. 010439, Final Supplement EIS, NOA, AK, Steller Sea Lion Protection Measures in the Alaska Groundfish Fisheries, Fishery Management Plans for Groundfish of the Gulf of Alaska and the Groundfish Fishery of the Bering Sea and Aleutian Islands Area, AK, *Wait Period Ends:* December 24, 2001, *Contact:* James W. Balsiger (907) 586–7221.

EIS No. 010440, Final EIS, FRC, WA, Cowlitz River Hydroelectric Project (No. 2016–044), Relicensing of the Existing 462-megawatt, Cowlitz River, City of Tacoma, WA, *Wait Period Ends:* December 24, 2001, *Contact:* David Turner (202) 219–2844.

EIS No. 010441, Final EIS, EPA, FL, Tampa Bay Regional Reservoir Project, Construction and Operation an 1100-acre Reservoir Facility, Hillsborough River, Tampa Bypass Canal and Alafia River, Hillsborough County, FL, *Wait Period Ends:* December 24, 2001, *Contact:* John Hamilton (404) 562–9617.

EIS No. 010442, Final EIS, COE, SD, Title VI Land Transfer South Dakota, Transfer of 91,178 Acres of Land at Lake Oahe, Lake Sharp, Lake Francise Case, and Lewis & Clark Lake, from the US Army Corps of Engineers (USACE) to the South Dakota Department of Game, Fish and Parks (SDGFP), SD, *Wait Period Ends:* December 24, 2001, *Contact:* Patty Freeman (402) 221–3803.

Amended Notices

EIS No. 010326, Draft EIS, APH, Programmatic—EIS Rangeland Grasshopper and Mormon Cricket Suppression Program, Authorization, Funding and Implementation in 17 Western States, AZ, CA, CO, ID, KS, MT, NB, NV, NM, ND, OK, OR, SD, TX, UT, WA and WY, *Comment Period Ends:* November 28, 2001, *Contact:* Charles L. Brown (301) 734–8247. Revision of FR Notice Published on 08/31/2001: CEQ Review Period Ending on 11/14/2001 has been Extended to 11/28/2001.

EIS No. 010367, Draft EIS, BIA, CA, NV, Truckee River Water Quality Settlement Agreement-Federal Water Right Acquisition, Implementation, Truckee River, Placer County, CA and Washoe, Storey and Lyon Counties, NV, *Comment Period Ends:* December 05, 2001, *Contact:* Tom Strekal (775) 887–3500. Published FR–10–05–01—Correction to Comment Period from 12–03–2001 to 12–05–2001.

EIS No. 010422, Draft Supplement, GSA, CA, Los Angeles Federal Building—U.S. Courthouse, Construction of a New Courthouse in the Civic Center, Additional Information, City of Los Angeles, Los Angeles County, CA, *Comment Period Ends:* December 31, 2001, *Contact:* Javad Soltani (415) 522–3493. Published FR 11–16–01 Correction to Document Status from Draft to Draft Supplement.

EIS No. 010423, Draft EIS, UAF, OK, Altus Air Force Base (AFB), Proposes Airfield Repairs, Improvements, and Adjustments to Aircrew Training, Install an Instrument Landing System (ILS) and a Microwave Landing System (MLS), Jackson County, OK, *Comment Period Ends:* December 31, 2001, *Contact:* Ron Voorhees (210) 652–3656. Published FR–09–21–01—Correction to State from IN to IL.

EIS No. 010426, Draft EIS, DOE, KY, Kentucky Pioneer Integrated Gasification Combined Cycle Demonstration Project, Constructing and Operating a 540 megawatt-electric Plant, Clean Coal Technology Program, Clark County, KY, *Comment Period Ends:* January 04, 2002, *Contact:* Roy Spears (304) 285–5460. Published FR—11–16–01 Correction to Comment Period from 12–31–2001 to 01–04–2002 also correction to Contact Person Phone # (304) 285–5460.

Dated: November 19, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–29275 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–60–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7106–9]

Office of Research and Development; Board of Scientific Counselors Subcommittee Review of the National Exposure Research Laboratory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of review.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C., App. 2) notification is hereby given that the Environmental Protection Agency, Office of Research and Development (ORD), Board of Scientific Counselors (BOSC), Subcommittee will meet to review the National Exposure Research Laboratory.

DATES: The review will be held on December 18–20, 2001. On Tuesday, December 18, 2001, the review will begin at 8 a.m., and will recess at 5 p.m. On Wednesday, December 19, 2001, the review will begin at 8:30 a.m. and recess at 5 p.m. On the final day, Thursday, December 20, 2001, the meeting will begin at 8:30 a.m. and adjourn 2:30 p.m., and will include a writing session from 8:45 a.m. to 12 noon. All times noted are Eastern Time.

ADDRESSES: The review will be held at the Catawba Building, 3210 Highway 54, Room 327, Research Triangle Park, North Carolina.

FOR FURTHER INFORMATION CONTACT: Shirley R. Hamilton, Designated Federal Officer, U.S. Environmental Protection Agency, Office of Research and Development, (8701R), 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 564–6853.

SUPPLEMENTARY INFORMATION: Anyone desiring a draft agenda may fax their request to Shirley R. Hamilton, (202) 565–2444. The meeting is open to the public. Any member of the public wishing to make comments at the meeting should contact Shirley Hamilton, Designated Federal Officer, U.S. Environmental Protection Agency, Board of Scientific Counselors, Office of Research and Development (8701R), 1200 Pennsylvania Avenue NW., Washington, DC 20460 by telephone at (202) 564–6853. In general, each individual making an oral presentation will be limited to a total of three minutes.

Dated: November 15, 2001.

Peter W. Preuss,

Director, National Center for Environmental Research.

[FR Doc. 01–29271 Filed 11–21–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. AUC–01–82–B (Auction No. 82); DA 01–2605]

Auction of Construction Permits for New Analog Television Stations Scheduled for February 5, 2002; Comment Sought on Reserve Prices or Minimum Opening Bids and Other Auction Procedural Issues

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the auction of four construction permits for new analog television stations to commence on February 5, 2002.

DATES: Comments are due on or before November 26, 2001, and reply comments are due on or before December 3, 2001.

ADDRESSES: An original and four copies of all pleadings must be filed with the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, Room TW–A325, 445 Twelfth Street, SW., Washington, DC 20054, in accordance with § 1.51(c) of the Commission's rules. In addition, commenters are requested to fax a courtesy copy of their comments and reply comments to the attention of Kathy Garland at (717) 338–2850.

FOR FURTHER INFORMATION CONTACT: Video Services Division: Shaun Maher at (202) 418–1600. Auctions and Industry Analysis Division: Kenneth Burnley, Legal Branch at (202) 418–0660 and Linda Sanderson, Operations Branch at (717) 338–2888. Requests for information can also be e-mailed to *auctionsinquiry@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction No. 82 Comment Public Notice* released November 9, 2001. The complete text of the *Auction No. 82 Comment Public Notice,* including attachments, is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The *Auction No. 82 Comment Public Notice* may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

1. By the *Auction No. 82 Comment Public Notice,* the Mass Media Bureau (''MMB'') and the Wireless Telecommunications Bureau (''WTB'') (collectively, ''Bureaus'') announce the auction of four construction permits for new analog television stations to commence on February 5, 2002 (''Auction No. 82''). A list of the channels and communities of these stations is included as Attachment A of the *Auction No. 82 Comment Public Notice.* These new television stations are the subject of pending, mutually exclusive short-form applications (FCC Form 175) filed on or before June 29, 2001. Pursuant to the *Broadcast First Report and Order,* 63 FR 48615 (September 11, 1998), participation in the auction will be limited to those applicants. A list of those applicants is also identified in Attachment A of the *Auction No. 82 Comment Public Notice.*

2. The Balanced Budget Act of 1997 requires the Commission to ''ensure that, in the scheduling of any competitive bidding under this subsection, an adequate period is allowed * * * before issuance of bidding rules, to permit notice and comment on proposed auction procedures. * * *'' Consistent with the provisions of the Balanced Budget Act and to ensure that potential bidders have adequate time to familiarize themselves with the specific rules that will govern the day-to-day conduct of an auction, the Commission directed the Bureaus, under their existing delegated authority, to seek comment on a variety of auction-specific procedures prior to the start of each auction. The Bureaus therefore seek comment on the following issues relating to Auction No. 82.

I. Auction Structure

A. Multiple Round Auction Design

3. The Bureaus propose to award these construction permits in a simultaneous multiple-round auction. As described further, this methodology offers every construction permit for bid at the same time with successive bidding rounds in which bidders may place bids. The Bureaus seek comment on this proposal.

B. Upfront Payments and Initial Maximum Eligibility

4. The upfront payment is a refundable deposit made by each bidder to determine and establish eligibility to

bid on the construction permits being auctioned. For Auction No. 82, the Bureaus propose to make the upfront payments equal to the minimum opening bids, which are established based on similar facts as described in section II.B. The specific upfront payments for each construction permit are set forth in Attachment A of the *Auction No. 82 Comment Public Notice.* The Bureaus seek comment on this proposal.

5. The upfront payment submitted by a bidder will determine the number of bidding units on which a bidder may place bids. This limit is a bidder's ''maximum initial eligibility.'' Each construction permit is assigned a specific number of bidding units equal to the upfront payment listed in Attachment A, on a bidding unit per dollar basis. This number does not change as prices rise during the auction. A bidder may place bids on multiple construction permits, if selected on the FCC Form 175, as long as the total number of bidding units associated with those construction permits does not exceed its maximum initial eligibility. Eligibility cannot be increased during the auction. Thus, in calculating its upfront payment amount, an applicant must determine the *maximum* number of bidding units it may wish to bid on (or hold high bids on) in any single round, and submit an upfront payment covering that number of bidding units. The Bureaus seek comment on this proposal.

C. Activity Rules

6. An activity rule requires bidders to bid actively on a percentage of their current bidding eligibility and/or be the standing high bidder during each round of the auction rather than waiting until the end to participate. The Bureaus propose a single stage auction with the following activity requirement: In each round of the auction, a bidder desiring to maintain its eligibility to participate in the auction is required to be active on one hundred (100) percent of its bidding eligibility. Failure to maintain the requisite activity level will result in the use of an activity rule waiver, if any remain, or a reduction in the bidder's bidding eligibility. The Bureaus seek comment on this proposal.

D. Activity Rule Waivers and Reducing Eligibility

7. Use of an activity rule waiver preserves the bidder's current bidding eligibility despite the bidder's activity in the current round being below the required activity level. An activity rule waiver applies to an entire round of bidding and not to a particular construction permit. Activity waivers are principally a mechanism for auction participants to avoid the loss of auction rather eligibility in the event that exigent circumstances prevent them from placing a bid in a particular round.

8. The FCC auction system assumes that bidders with insufficient activity would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver (known as an ''automatic waiver'') at the end of any bidding period where a bidder's activity is below the required activity level unless: (i) There are no activity rule waivers available; or (ii) the bidder overrides the automatic application of a waiver by reducing eligibility, thereby meeting the minimum requirements. If a bidder has no waivers remaining and does not satisfy the required activity level, the system will permanently reduce their current eligibility to bring them into compliance with the activity rule.

9. A bidder with insufficient activity may wish to reduce its bidding eligibility rather than use an activity rule waiver. If so, the bidder must affirmatively override the automatic waiver mechanism during the bidding period by using the reduce eligibility function in the bidding system. In this case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rules as described. Once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility.

10. A bidder may proactively use an activity rule waiver as a means to keep the auction open without placing a bid. If a bidder submits a proactive waiver (using the Proactive Waiver function in the bidding system) during a bidding period in which no bids or withdrawals are submitted, the auction will remain open and the bidder's eligibility will be preserved. An automatic waiver invoked in a round in which there are no new valid bids will not keep the auction open.

11. The Bureaus propose that each bidder in Auction No. 82 be provided with three activity rule waivers that may be used at the bidder's discretion during the course of the auction as set forth. The Bureaus seek comment on this proposal.

E. Information Relating to Auction Delay, Suspension or Cancellation

12. For Auction No. 82, the Bureaus propose that, by public notice or by announcement during the auction, they may delay, suspend or cancel the auction in the event of natural disaster or national emergency, technical obstacle, evidence of an auction security breach, unlawful bidding activity, administrative or weather necessity, or for any other reason that affects the fair and competitive conduct of competitive bidding. In such cases, the Bureaus, in their sole discretion, may elect to resume the auction starting from the beginning of the current round, resume the auction starting from some previous round, or cancel the auction in its entirety. Network interruption may cause the Bureaus to delay or suspend the auction. The Bureaus emphasize that exercise of this authority is solely within its discretion and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers. The Bureaus seek comment on this proposal.

II. Bidding Procedures

A. Round Structure

13. The Commission will use its Automated Auction System to conduct the electronic simultaneous multiple round auction format for Auction No. 82. Auction No. 82 will be conducted over the Internet. However, as in prior auctions, the FCC Wide Area Network will be available at the standard charge, and telephonic bidding will also be available. Prospective bidders concerned about their access to the Internet may want to establish a connection to the FCC Wide Area Network as a backup. Full information regarding how to establish such a connection, and related charges, will be provided in the public notice announcing details of auction procedures.

14. In past auctions, the Bureaus have used the timing of bids to select a high bidder when multiple bidders submit identical high bids on a construction permit in a given round. Given that bidders will access the Internet at differing speeds, the Bureaus will not use this procedure in Auction No. 82. For Auction No. 82, the Bureaus propose to use a random number generator to select a high bidder from among such bidders. As with prior auctions, remaining bidders will be able to submit higher bids in subsequent rounds. The initial bidding schedule will be announced in a public notice to be released at least one week before the start of the auction, and will be included in the registration mailings. The simultaneous multiple round format will consist of sequential bidding rounds, each followed by the release of round results. Details regarding the location and format of round results will be included in the same public notice.

15. The Bureaus have discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. The Bureaus may increase or decrease the amount of time for the bidding rounds and review periods, or the number of rounds per day, depending upon the bidding activity level and other factors. The Bureaus seek comment on this proposal.

B. Reserve Price or Minimum Opening Bid

16. The Balanced Budget Act calls upon the Commission to prescribe methods by which a reasonable reserve price will be required or a minimum opening bid established when FCC licenses or construction permits are subject to auction (*i.e.,* when the Commission has accepted mutually exclusive applications for licenses or construction permits), unless the Commission determines that a reserve price or minimum bid is not in the public interest. Consistent with this mandate, the Commission has directed the Bureaus to seek comment on the use of minimum opening bids and/or reserve price prior to the start of each auction.

17. Normally, a reserve price is an absolute minimum price below which an item will not be sold in a given auction. Reserve prices can be either published or unpublished. A minimum opening bid, on the other hand, is the minimum bid price set at the beginning of the auction below which *no* bids are accepted. It is generally used to accelerate the competitive bidding process. Also, in a minimum opening bid scenario, the auctioneer generally has the discretion to lower the amount later in the auction. It is also possible for the minimum opening bid and the reserve price to be the same amount.

18. In light of the Balanced Budget Act's requirements, the Bureaus propose to establish a minimum opening bid for Auction No. 82. The Bureaus believe a minimum opening bid, which has been utilized in other auctions, is an effective bidding tool. A minimum opening bid, rather than a reserve price, will help to regulate the pace of the auction and provides flexibility.

19. For Auction No. 82, the proposed minimum opening bid prices were determined by taking into account various factors related to the efficiency of the auction and the potential value of the spectrum, including the type of service, market size, industry cash flow data and recent broadcast transactions. The specific minimum opening bid for each construction permit is set forth in Attachment A of the *Auction No. 82 Comment Public Notice.* The Bureaus seek comment on this proposal.

20. If commenters believe that these minimum opening bids will result in unsold construction permits, or are not reasonable amounts, or should instead operate as reserve prices, they should explain why this is so, and comment on the desirability of an alternative approach. Commenters are advised to support their claims with valuation analyses and suggested reserve prices or minimum opening bid levels or formulas. Alternatively, comment is sought on whether, consistent with the Balanced Budget Act, the public interest would be served by having no minimum opening bid or reserve price.

C. Minimum Accepted Bids and Bid Increments

21. In each round, eligible bidders will be able to place bids on a given construction permit in any of nine different amounts. The Automated Auction System interface will list the nine acceptable bid amounts for each construction permit. Once there is a standing high bid on the construction permit, the Automated Auction System will calculate a minimum acceptable bid for that construction permit for the following round, as described. The difference between the minimum acceptable bid and the standing high bid for each construction permit will define the *bid increment.* The nine acceptable bid amounts for each construction permit consist of the minimum acceptable bid (the standing high bid plus one bid increment) and additional amounts calculated using multiple bid increments (*i.e.,* the second bid amount equals the standing high bid plus two times the bid increment, the third bid amount equals the standing high bid plus three times the bid increment, etc.).

22. Until a bid has been placed on a construction permit, the minimum acceptable bid for that construction permit will be equal to its minimum opening bid. The additional bid amounts for construction permits that have not yet received a bid will be calculated differently, as explained.

23. For Auction No. 82, the Bureaus propose to calculate minimum acceptable bids by using a smoothing methodology, as they have done in several other auctions. The smoothing formula calculates minimum acceptable bids by first calculating a *percentage increment,* not to be confused with the *bid increment,* for each construction permit based on a weighted average of the activity received on each construction permit in all previous rounds. This methodology tailors the percentage increment for each construction permit based on activity, rather than setting a global increment for all construction permits.

24. In a given round, the calculation of the percentage increment for each construction permit is made at the end of the previous round. The computation is based on an activity index, which is calculated as the weighted average of the activity in that round and the activity index from the prior round. The activity index at the start of the auction (round 0) will be set at 0. The current activity index is equal to a weighting factor times the number of new bids received on the construction permit in the most recent bidding round plus one minus the weighting factor times the activity index from the prior round. The activity index is then used to calculate a percentage increment by multiplying a minimum percentage increment by one plus the activity index with that result being subject to a maximum percentage increment. The Commission will initially set the weighting factor at 0.5, the minimum percentage increment at 0.1 (10%), and the maximum percentage increment at 0.2 (20%).

Equations

$A_i = (C * B_i) + ((1–C) * A_{i-1})$

I_{i+1} = smaller of $((1 + A_i) * N)$ and M

$X_{i+1} = I_{i+1} * Y_i$

where,

A_i = activity index for the current round (round i)

C = activity weight factor

B_i = number of bids in the current round (round i)

A_{i-1} = activity index from previous round (round i–1), A_0 is 0

I_{i+1} = percentage increment for the next round (round i+1)

N = minimum percentage increment or percentage increment floor

M = maximum percentage increment or percentage increment ceiling

X_{i+1} = dollar amount associated with the percentage increment

Y_i = high bid from the current round

25. Under the smoothing methodology, once a bid has been received on a construction permit, the minimum acceptable bid for that construction permit in the following round will be the high bid from the current round plus the dollar amount associated with the percentage increment, with the result rounded to the nearest thousand if it is over $10,000, to the nearest hundred if it is under $10,000 but over $1,000, or to the nearest ten if it is below $1,000.

Examples

Construction Permit 1

C = 0.5, N = 0.1, M = 0.2

Round 1 (2 new bids, high bid = $1,000,000)

i. Calculation of percentage increment for round 2 using the smoothing formula:
$A_1 = (0.5 * 2) + (0.5 * 0) = 1$
I_2 = The smaller of ((1 + 1) * 0.1) = 0.2 or 0.2 (the maximum percentage increment)

ii. Calculation of dollar amount associated with the percentage increment for round 2 (using I_2):
$X_2 = 0.2 * \$1{,}000{,}000 = \$200{,}000$

iii. Minimum acceptable bid for round 2 = $1,200,000

Round 2 (3 new bids, high bid = $2,000,000)

i. Calculation of percentage increment for round 3 using the smoothing formula:
$A_2 = (0.5 * 3) + (0.5 * 1) = 2$
I_3 = The smaller of ((1 + 2) * 0.1) = 0.3 or 0.2 (the maximum percentage increment)

ii. Calculation of dollar amount associated with the percentage increment for round 3 (using I_3):
$X_3 = 0.2 * \$2{,}000{,}000 = \$400{,}000$

iii. Minimum acceptable bid for round 3 = $2,400,000

Round 3 (1 new bid, high bid = $2,400,000)

i. Calculation of percentage increment for round 4 using the smoothing formula:
$A_3 = (0.5 * 1) + (0.5 * 2) = 1.5$
I_4 = The smaller of ((1 + 1.5) * 0.1) = 0.25 or 0.2 (the maximum percentage increment)

ii. Calculation of dollar amount associated with the percentage increment for round 4 (using I_4):
$X_4 = 0.2 * \$2{,}400{,}000 = \$480{,}000$

iii. Minimum acceptable bid for round 4 = $2,880,000

26. As stated, until a bid has been placed on a construction permit, the minimum acceptable bid for that construction permit will be equal to its minimum opening bid. The additional bid amounts are calculated using the difference between the minimum opening bid times one plus the minimum percentage increment, rounded as described, and the minimum opening bid. That is, I = (minimum opening bid)(1 + N){rounded}–(minimum opening bid). Therefore, when N equals 0.1, the first additional bid amount will be approximately ten percent higher than the minimum opening bid; the second, twenty percent; the third, thirty percent; etc.

27. In the case of a construction permit for which the standing high bid has been withdrawn, the minimum acceptable bid will equal the second highest bid received for the construction permit. The additional bid amounts are calculated using the difference between the second highest bid times one plus the minimum percentage increment, rounded, and the second highest bid.

28. The Bureaus retain the discretion to change the minimum acceptable bids and bid increments if it determines that circumstances so dictate. The Bureaus will do so by announcement in the Automated Auction System. The Bureaus seek comment on these proposals.

D. Information Regarding Bid Withdrawal and Bid Removal

29. For Auction No. 82, the Bureaus propose the following bid removal and bid withdrawal procedures. Before the close of a bidding period, a bidder has the option of removing any bid placed in that round. By using the Remove Selected Bids function in the bidding system, a bidder may effectively ''unsubmit'' any bid placed within that round. A bidder removing a bid placed in the same round is not subject to a withdrawal payment.

30. Once a round closes, a bidder may no longer remove a bid. However, in any subsequent round, a high bidder may withdraw its standing high bids from previous rounds using the Withdraw function in the bidding system. A high bidder that withdraws its standing high bid from a previous round is subject to the bid withdrawal payment provisions of the Commission rules. The Bureaus seek comment on these bid removal and bid withdrawal procedures.

31. The Bureaus propose to limit each bidder in Auction No. 82 to withdrawing standing high bids in no more than one round during the course of the auction. To permit a bidder to withdraw bids in more than one round would likely encourage insincere bidding or the use of withdrawals for anti-competitive purposes. The round in which withdrawals are utilized will be at the bidder's discretion; withdrawals otherwise must be in accordance with the Commission's rules. There is no limit on the number of standing high bids that may be withdrawn in the round in which withdrawals are utilized. Withdrawals will remain subject to the bid withdrawal payment provisions specified in the Commission's rules. The Bureaus seek comment on this proposal.

E. Stopping Rule

32. For Auction No. 82, the Bureaus propose to employ a simultaneous stopping rule approach. The Bureaus have discretion ''to establish stopping rules before or during multiple round auctions in order to terminate the auction within a reasonable time.'' A simultaneous stopping rule means that all construction permits remains open until the first round in which no new acceptable bids, proactive waivers, or withdrawals are received. After the first such round, bidding closes simultaneously on all construction permits. Thus, unless circumstances dictate otherwise, bidding would remain open until bidding stops on all construction permits.

33. However, the Bureaus propose to retain the discretion to exercise any of the following options during Auction No. 82:

i. Utilize a modified version of the simultaneous stopping rule. The modified stopping rule would close the auction for all construction permits after the first round in which no bidder submits a proactive waiver, withdrawal, or a new bid on any construction permit on which it is not the standing high bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a construction permit for which it is the standing high bidder would not keep the auction open under this modified stopping rule.

ii. Keep the auction open even if no new acceptable bids or proactive waivers are submitted and no previous high bids are withdrawn. In this event, the effect will be the same as if a bidder had submitted a proactive waiver. The activity rule, therefore, will apply as usual, and a bidder with insufficient activity will either lose bidding eligibility or use a remaining activity rule waiver.

iii. Declare that the auction will end after a specified number of additional rounds (''special stopping rule''). If the Bureaus invoke this special stopping rule, it will accept bids in the specified final round(s) only for construction permits on which the high bid increased in at least one of the preceding specified number of rounds.

34. The Bureaus propose to exercise these options only in certain circumstances, such as, for example, where the auction is proceeding very slowly, there is minimal overall bidding activity, or it appears likely that the auction will not close within a reasonable period of time. Before exercising this option, the Bureaus are likely to attempt to increase the pace of the auction by, for example, increasing the number of bidding rounds per day, and/or increasing the amount of the minimum bid increments for the limited number of construction permits where there is still a high level of bidding

activity. The Bureaus seek comment on these proposals.

III. Due Diligence

35. Potential bidders are solely responsible for investigating and evaluating all technical and market place factors that may have a bearing on the value of the television facilities in this auction. The FCC makes no representations or warranties about the use of this spectrum for particular services. Applicants should be aware that a FCC auction represents an opportunity to become a FCC permittee in the broadcast service, subject to certain conditions and regulations. A FCC auction does not constitute an endorsement by the FCC of any particular service, technology, or product, nor does a FCC construction permit or license constitute a guarantee of business success. Applicants should perform their individual due diligence before proceeding as they would with any new business venture.

36. Potential bidders are strongly encouraged to conduct their own research prior to Auction No. 82 in order to determine the existence of pending proceedings that might affect their decisions regarding participation in the auction. Participants in Auction No. 82 are strongly encouraged to continue such research during the auction.

37. Potential bidders should note that, in November 1999, Congress enacted the Community Broadcasters Protection Act of 1999 (CBPA) which established a new Class A television service. In response to the enactment of the CBPA, the Commission adopted rules to establish the new Class A television service. In the *Class A Report and Order,* the Commission adopted rules to provide interference protection for eligible Class A television stations from new full power television stations. Given the Commission's ruling in the *Class A Report and Order,* the winning bidders in Auction No. 82, upon submission of their long-form applications (FCC Form 301), will have to provide interference protection to qualified Class A television stations. Therefore, potential bidders are encouraged to perform engineering studies to determine the existence of Class A television stations and their effect on the ability to operate the full power television stations proposed in this auction. Information about the identity and location of Class A television stations is available from the Mass Media Bureau's Consolidated Database System (CDBS) (public access available at: *http://www.fcc.gov/mmb*) and on the Mass Media Bureau's Class A television web page: *http://www.fcc.gov/mmb/vsd/files/classa.html.*

38. Potential bidders are also reminded that full service television stations are in the process of converting from analog to digital operation and that stations may have pending applications to construct and operate digital television facilities, construction permits and/or licenses for such digital facilities. Bidders should investigate the impact such applications, permits and licenses may have on their ability to operate the facilities proposed in this auction.

IV. Prohibition of Collusion

39. Bidders are reminded that § 1.2105(c) of the Commission's rules prohibits applicants for the same geographic license area from communicating with each other during the auction about bids, bidding strategies, or settlements unless they have identified each other as parties with whom they have entered into agreements under § 1.2105(a)(2)(viii). For Auction No. 82, this prohibition became effective at the short-form application filing deadline on Friday, June 29, 2001, and will end on the post-auction down payment deadline, which will be announced in a future public notice. If parties had agreed in principle on all material terms, those parties must have been identified on the short-form application under § 1.2105(c), even if the agreement had not been reduced to writing. If parties had not agreed in principle by the filing deadline, an applicant should not have included the names of those parties on its application, and must not have continued negotiations with other applicants for licenses in the same geographic area.

40. In addition, § 1.65 of the Commission's rules requires an applicant to *maintain* the accuracy and completeness of information furnished in its pending application and to notify the Commission within 30 days of any substantial change that may be of decisional importance to that application. Thus, § 1.65 requires an auction applicant to notify the Commission of any violation of the anti-collusion rules upon learning of such violation. Bidders therefore are required to make such notification to the Commission immediately upon discovery. In the *Competitive Bidding Seventh Report & Order,* 66 FR 54447 (October 29, 2001), the Commission amended § 1.2105 to require auction applicants to report prohibited communications in writing to the Commission immediately, but in no case later than five business days after the communication occurs.

V. Maintaining the Accuracy of FCC Form 175 Information

41. As noted in the *Auction No. 82 Filing Window Public Notice,* 66 FR 33699 (June 25, 2001), after the short-form filing deadline, applicants may make only minor changes to their FCC Form 175 applications. For example, permissible minor changes include deletion and addition of authorized bidders (to a maximum of three) and certain revision of exhibits. At this time, filers must submit a letter summarizing the changes to: Margaret Wiener, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, Federal Communications Commission, 445 12th Street, SW, Room 4–A760, Washington, DC 20554.

42. A separate copy of the letter should be mailed to Shaun Maher, Video Services Division, Mass Media Bureau, Federal Communications Commission, 445 12th Street, SW, Room 2–A820, Washington, DC 20554 and faxed to the attention of Kathryn Garland at (717) 338–2850. Questions about other changes should be directed to Shaun Maher at (202) 418–1600.

VI. Conclusion

43. Comments are due on or before November 26, 2001, and reply comments are due on or before December 3, 2001. An original and four copies of all pleadings must be filed with the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, Room TW–A325, 445 Twelfth Street, SW., Washington, DC 20054, in accordance with § 1.51(c) of the Commission's rules. See 47 CFR 1.51(c). In addition, one copy of each pleading must be delivered to each of the following locations: (i) The Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY–B402, Washington, DC 20554; (ii) Office of Media Relations, Public Reference Center, 445 Twelfth Street, SW., Suite CY–A257, Washington, DC 20554; (iii) Rana Shuler, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, 445 Twelfth Street, SW., Suite 4–A628, Washington, DC 20554; (iv) Shaun Maher, Video Services Division, Mass Media Bureau, 445 Twelfth Street, SW., Suite 2–A820, Washington, DC 20554. Applicants that send their comments via Federal Express or any other express mail service should use the zip code ''20024.'' Hand-delivered or messenger-delivered comments will be accepted at

9300 East Hampton Drive, Capital Heights, Maryland, 20743. Comments and reply comments will be available for public inspection during regular business hours in the FCC Public Reference Room, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. In addition, the Bureaus request that commenters fax a courtesy copy of their comments and reply comments to the attention of Kathryn Garland at (717) 338–2850.

44. This proceeding has been designated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules.

Federal Communications Commission.

Margaret Wiener,

Chief, Auctions and Industry Analysis Division, WTB.

[FR Doc. 01–29366 Filed 11–21–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 17, 2001.

A. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309–4470:

1. First Columbia Bancorp, Inc., Lake City, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Columbia County Bank, Lake City, Florida.

B. Federal Reserve Bank of Kansas City (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. Central Financial Corporation, Hutchinson, Kansas; to acquire additional shares, for a total of 8.9 percent of the voting shares of NorthStar Bancshares, Inc., Kansas City, Missouri, and thereby indirectly acquire voting shares of NorthStar Bank, Kansas City, Missouri.

Board of Governors of the Federal Reserve System, November 16, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–29178 Filed 11–21–01; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Support Center; Statement of Organization, Functions, and Delegations of Authority

Part P, Program Support Center (PSC), Statement of Organization, Functions and Delegations of authority for the Department of Health and Human Services (HHS) (66 FR 31240–41, October 2, 1995, and as last amended at 66 FR 35981–82, July 10, 2001) is being amended to reflect a change in the reporting relationship of the PSC Director, within HHS. The PSC Director will receive directions from the Deputy Assistant Secretary for Management and Operations, Office of Management and Operations (AJC), Office of the Assistant Secretary for Administration and Management (AJ). The changes are as follows:

I. Under Chapter P, paragraph P.10 Organization, replace with the following:

P.10 Organization. The Program Support Center is a component within HHS to provide a wide range of support and administrative services to HHS components and other Federal agencies. The Program Support Center shall be under the direction of a Director, who receives day-to-day guidance from the Deputy Assistant Secretary for Management and Operations, Office of Management and Operations (AJC), who reports to the Assistant Secretary for Administration and Management (AJ).

II. Under Paragraph P.20 Functions, paragraph A. ''Office of the Director,'' replace with the following:

A. *Office of the Director (PA).* The PSC Director is responsible to the Deputy Assistant Secretary for Management and Operations, Office of Management and Operations, Office of the Assistant Secretary for Administration and Management, in managing and directing the PSC. The Office functions include (1) providing leadership for the implementation of the PSC responsibilities in accomplishing its mission, (2) providing staff support to the Director of the PSC; (3) developing customer service strategic and marketing plans; and (4) coordinating publication of reports to HHS management, customers and employees.

III. Continuations of Regulations

Except as inconsistent with this reorganization, all regulations, rules, orders, statements of policy and interpretations with respect to the Program Support Center heretofore issued and in effect prior to the date of this Reorganization, or to become effective subsequent to said date are continued in full force and effect.

IV. Prior Statements of Organizations, Functions, and Delegations of Authority

A. All delegations of authorities made to the PSC components, and all further redelegations of such authorities in effect immediately prior to the effective date of this Reorganization shall continue in effect pending further redelegation.

B. To the extent inconsistent with this Reorganization, all previous statements of organizations, functions, delegations of authority, as well as applicable present Chapters of Part P, of the Department's Organizational Manual shall remain unchanged, pending further changes by the Assistant Secretary for Administration and Management.

Dated: November 14, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–29175 Filed 11–21–01; 8:45 am]

BILLING CODE 4166–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Committee on Immunization Practices (ACIP) Teleconference.

Times and Dates: 1:30 p.m.–4:30 p.m., December 7, 2001.

Place: Teleconference call will originate at the Centers for Disease Control and Prevention in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The teleconference agenda will include a discussion of the use of pneumococcal conjugate vaccine (PCV–7) and diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) in response to shortages of PCV–7 and DTaP, and use of pediatric vaccines containing thimerosal. Agenda items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This conference call is scheduled for 1:30 p.m. Eastern Standard Time. To access the teleconference you must dial 1/888/556–5771. International callers should dial 712–257–2273. To be connected to the call, you will need to provide the attendant with the pass code ''ACIP meeting'' and leader name Gloria Kovach. You will then be automatically connected to the call.

CONTACT PERSON FOR MORE INFORMATION: Gloria A. Kovach, Program Analyst, Epidemiology and Surveillance Division, National Immunization Program, CDC,1600 Clifton Road, NE, m/s E61, Atlanta, Georgia 30333. Telephone 404/639–8096.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 16, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–29216 Filed 11–21–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–R–305]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* External Quality Review of Medicaid MCOs and Supporting Regulations in 42 CFR 438.352,438.360, 438.362, and 438.36; *Form No.:* CMS-R–305 (OMB# 0938–0786); *Use:* The results of Medicare reviews, Medicare accreditation surveys, and Medicaid external quality reviews will be used by States in assessing the quality of care provided to Medicaid beneficiaries provided by managed care organizations or to provide information on the quality of the care provided to the general public upon request. Three of the protocol activities are mandatory and six are optional; *Frequency:* Annually; *Affected Public:* Business or other for-profit, State, local or tribal govt.; *Number of Respondents:* 542; *Total Annual Responses:* 16,237; *Total Annual Hours:* 638,324.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS-R–305, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 16, 2001.

Julie E. Brown,

Acting Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–29231 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3077–N]

Medicare Program; Withdrawal of Medicare Coverage of Certain Positron Emission Tomography (PET) Scanners

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to withdraw Medicare coverage from certain 2-[F–18] Fluoro-D-Glucose Positron Emission Tomography (PET) scanners.

EFFECTIVE DATE: This notice is effective January 1, 2002 for clinical indications already covered by Medicare for 2-[F–18] Fluoro-D-Glucose PET scans before July 1, 2001.

FOR FURTHER INFORMATION CONTACT: Mitchell Burken, M.D., (410) 786–6861.

SUPPLEMENTARY INFORMATION: On April 27, 1999, we published a notice (64 FR 22619) that established the procedures used for making national coverage decisions. The April 27, 1999 notice also described the procedures we used to implement national coverage decisions. Under that section of the notice, we stated that if we chose to ''withdraw or reduce coverage for a service,'' we would publish the decision as a general notice in the **Federal Register**.

This notice announces our decision to reduce Medicare coverage of certain 2-[F–18] Fluoro-D-Glucose (FDG) Positron Emission Tomography (PET) scanners. For those clinical indications already covered by Medicare before July 1, 2001, PET imaging must be performed on either FDA-approved full- or partial-ring scanners, or coincidence systems that have the following features:

- Crystal at least 5/8-inch thick.
- Techniques to minimize or correct for scatter and/or randoms.
- Digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8-inch will not be covered. In addition, scans performed with systems with crystals greater than or equal to 5/8-inch in thickness, which do not meet the other listed design characteristics, are not covered.

Authority: Sections 1862, 1869(b)(3), and 1871 of the Social Security Act (42 U.S.C. 1395y, 1395ff(b)(3), and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 7, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–28807 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3079–N]

Medicare Program; Meeting of the Diagnostic Imaging Panel of the Medicare Coverage Advisory Committee—January 10, 2002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Diagnostic Imaging Panel (the Panel) of the Medicare Coverage Advisory Committee (the Committee). The Panel provides advice and recommendations to the Committee about clinical issues. The Panel will hear and discuss presentations from interested persons regarding whether and when it is scientifically justified to use FDG Positron Emission Tomography (PET) or other neuroimaging devices for the diagnosis and patient management of those with Alzheimer's disease (AD). The focus is on the marginal contribution of FDG-PET in various common clinical scenarios to patient outcomes. The following three scenarios will be evaluated:

- Asymptomatic patients who are at high risk of AD due to positive family history.
- Patients with mild cognitive impairment or similar syndrome.
- Patients with dementia.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* January 10, 2002 from 8 a.m. until 4:30 p.m., E.D.T.

Deadline for Presentations and Comments: December 27, 2001, 5 p.m., E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by December 20, 2001 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 327–328, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Janet A. Anderson, Executive Secretary; Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.hcfa.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Janet A. Anderson, Executive Secretary, 410–786–2700.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice in the **Federal Register** (64 FR 44231) to describe the Medicare Coverage Advisory Committee (the Committee), which provides advice and recommendations to us about clinical issues. This notice announces the following public meeting of the Diagnostic Imaging Panel (the Panel) of the Committee.

Current Panel Members:

Frank Papatheofanis, M.D., Ph.D.; Barbara McNeil, M.D., Ph.D.; Carole Flamm, M.D., M.P.H.; Jeffrey Lerner, Ph.D.; Michael Manyak, M.D.; Donna Novak, B.A.; Manuel Cerqueira, M.D.; Kim Burchiel, M.D.; Steven Guyton, M.D.; Sally Hart, J.D.; and Michael Klein, M.B.A.

Meeting Topic:

The Panel will hear and discuss presentations from interested persons regarding FDG Positron Emission Tomography (PET) imaging for Alzheimer's disease (AD), mild cognitive impairment, and dementia.

Procedure and Agenda:

This meeting is open to the public. The Panel will hear oral presentations from the public for approximately 90 minutes. The Panel may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section, and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Panel member before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or

services being discussed (or with their competitors).

After the public and CMS presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. The Panel will also allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Panel will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 14, 2001.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 01–29210 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1190–NC]

Medicare Program; Establishment of Procedures That Permit Public Consultation Under the Existing Process for Making Coding and Payment Determinations for New Clinical Laboratory Tests and for New Durable Medical Equipment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of public meetings with comment period.

SUMMARY: This notice announces the addition of public meetings under our existing process for making coding and payment determinations for new clinical laboratory tests and new durable medical equipment (DME). Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000(BIPA) requires us to establish procedures that permit public consultation for coding and payment determinations for new clinical laboratory tests and for new DME in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD–9–CM).

In addition, this notice announces the dates and general details of public meetings to be held in 2002. We are requesting comments on our plan to fulfill the requirements of section 531(b) of BIPA.

DATES: *Laboratory Public Meeting:* The meeting regarding the assignment of payment rates for new laboratory tests to be included in Medicare's Clinical Laboratory Fee Schedule for calendar year 2003 is scheduled for Monday, August 5, 2002. The meeting will begin at 8:30 a.m. and end at 4:30 p.m., E.S.T. The development of the codes for clinical laboratory tests is largely performed by the Current Procedural Terminology (CPT) Editorial Panel and will not be further discussed at the CMS meeting.

DME Public Meeting Dates: There will be three meetings regarding coding and payment for new DME. The meetings are scheduled for March 11, 2002, May 13, 2002, and June 17, 2002. All three meetings will begin at 8 a.m. and end at 5 p.m., E.S.T.

Comment Date: We are requesting comments on the procedures in this notice for establishing public consultation on our existing coding and payment determinations for new clinical laboratory tests and new DME. Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 22, 2002.

ADDRESSES: *Meetings:* All four meetings in 2002 will be held at the Centers for Medicare & Medicaid Services, CMS Auditorium, 7500 Security Boulevard, Baltimore, MD 21244.

Website: For clinical laboratory tests, a summary of the August 2002 meeting will be posted on our website (*www.hcfa.gov/audience/planprov.htm*) within 1 month after the meeting.

For DME items, you may access up-to-date meeting information on the HCPCS website at: *http://www.hcfa.gov/medicare/hcpcs.htm.*

Comments: Mail an original and three copies of written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1190–NC, P.O. Box 8017, Baltimore, MD 21244–8017.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them. If you prefer, you may deliver an original and three copies of your written comments to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1190–NC. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anita Greenberg, (410) 786–4601 for clinical laboratory payment rates; Kaye Riley, (410) 786–5323 for HCPCS coding for DME items; Joel Kaiser, (410) 786–4499 for DME payment rates.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554. Section 531(b) of BIPA mandates that we establish, no later than 1 year after the date of enactment, procedures that permit public consultation for coding and payment determinations for new clinical diagnostic laboratory tests and new DME under Part B of title XVIII of the Social Security Act (the Act) in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM. The ICD–9–CM process involves holding regularly scheduled public meetings that are announced in the **Federal Register** 30 days before the meeting date. The ICD–9–CM meetings are open to the public and are held in the CMS auditorium. The agenda for each meeting is posted on the CMS website before each meeting under the heading for meetings and announcements. A preliminary ICD–9–CM coding determination for each agenda item is presented by CMS at the meeting.

The procedures and public meetings announced in this notice for new clinical laboratory tests and new DME are in response to the mandate of section 531(b) of BIPA. Also, our HCPCS website at *http//www.hcfa.gov/medicare/hcpcs.htm* includes a description of our existing HCPCS

coding process and the additional public consultation process. The website provides a detailed explanation of the procedures we use to make coding and payment determinations for DME and other items and services that are coded in the HCPCS. We may make modifications to our process in the future as a result of comments we receive or based on our experience in implementing these procedures in 2002 and subsequent years.

II. Public Meetings

Registration

Deadline for Registration: Individuals must register for the meetings by the following dates:

DME meeting dates	Registration dates
March 11, 2002	January 28, 2002.
May 13, 2002	April 1, 2002.
June 17, 2002	May 3, 2002.
Laboratory meeting date	**Registration date**
August 5, 2002	July 24, 2002.

Presentations

Laboratory Agenda Item: Individuals who want to make a presentation on the Laboratory agenda item must register by sending a fax to the attention of Anita Greenberg at (410) 786–0169, no later than July 24, 2002. Please provide name, company name, address, and telephone number.

DME Agenda Item: Individuals who want to make presentations on a DME agenda item must register by sending a fax to the attention of Joel Kaiser at (410) 786–0765, by the registration dates listed above. Please provide name, company name, address, telephone number, and agenda item you want to address.

The agenda will consist of HCPCS coding requests for new DME. Requests must be submitted through the HCPCS coding process to Kaye Riley; Center for Medicare Management; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C5–08–27; Baltimore, MD 21244. Requests must be received by April 1 of each year in order to be considered during the review cycle for the next annual HCPCS update. The annual HCPCS update is January 1 of each year. Requests will be reviewed by CMS's HCPCS Alpha-Numeric Workgroup, which will make CMS's preliminary recommendation on what action needs to be taken in response to the request. Once the Workgroup's preliminary recommendation has been developed, the request will be added to the agenda for the next available public meeting.

General Information

The meetings will be held in a government building; therefore, security measures will be applicable. Anyone without government identification will need to present photo identification, sign-in, and provide registration information.

Persons attending the meetings in Baltimore who are hearing or visually impaired and have special requirements or a condition that requires special assistance or accommodations, should notify the individuals listed below.

Laboratory Meeting: Anita Greenberg at fax number (410) 786–0169 or call (410) 786–4601.

DME Meetings: Joel Kaiser at fax number (410) 786–0765 or call (410) 786–4499.

Purpose of the Meetings

New Laboratory Tests: The introduction of new codes may call for us to determine the rates at which the new codes will be paid. The laboratory meeting is intended to provide us with expert input on the nature of new tests before rate determinations are made. Discussion will be limited to the codes listed on the CMS Internet website at *www.hcfa.gov/audience/planprov.htm* by June 26, 2002.

New DME: Beginning in March 2002, CMS plans to schedule three public meetings per year on coding and pricing of new DME that will allow interested parties the opportunity to make oral presentations and submit written comments regarding coding and pricing recommendations for new DME that have been submitted using the HCPCS coding modification process. These public meetings will be held during the months of March, May, and June. Each meeting will be a full day.

Before each public meeting, the HCPCS workgroup will meet to review the coding requests that will be on the agenda for the next public meeting. In advance of a meeting, the Workgroup will complete a fact sheet that will include the following information for each agenda item:

- The nature of the request for a coding modification.
- Background information pertinent to the request.
- The fact sheet will also include for each request on the agenda the HCPCS workgroup's preliminary recommendation, and the rationale for this recommendation.

In addition, the fact sheet will also include the Workgroup's preliminary recommendation regarding the applicable payment category and the methodology that will be used to set a payment amount, for example, supplier price lists, price of a comparable item, or reasonable charge data. The preliminary recommendations of the HCPCS workgroup regarding the coding requests and CMS's preliminary payment methodology decision will be presented at the public meetings for discussion. After a public meeting, the workgroup will reconsider its preliminary coding recommendations, and CMS staff will reconsider pricing recommendations in view of the information presented at the public meeting. After reconsidering its preliminary coding recommendations in light of the discussions at the public meeting, the workgroup will decide what recommendations it should make to the HCPCS National Alpha-Numeric Editorial Panel, the entity that maintains the permanent HCPCS level II codes and that is hereafter referred to as the National Panel. The HCPCS National Panel is comprised of the Health Insurance Association of America, the Blue Cross and Blue Shield Association, and CMS.

Format and Agenda

New Laboratory Tests: This meeting is open to the public. The on-site check-in for visitors who have registered to attend the meeting will be held from 8 a.m. to 8:30 a.m., followed by opening remarks. Registered persons from the public may present discussion and individual recommendations on payment determinations for specific new Current Procedural Terminology (CPT–4) codes for the 2003 Clinical Laboratory Fee Schedule, which are to become effective January 1, 2003. A newly created CPT–4 code can represent either a refinement or modification of existing test methods, or a substantially new test method. Decisions regarding payment levels or methods for determining them for the newly created CPT–4 codes will not be made at this meeting. However, the meeting will provide an opportunity for us to receive public input before we determine payments for the new codes. All presentations should be brief, and three written copies should be submitted to accompany any oral presentations. Information we find helpful for presenters to address includes the nature of the test method, applications, costs, and any recommendation the presenter may have regarding the method for establishing a payment rate (as discussed below). Due to time constraints, we may limit the number and duration of oral presentations to fit the time available. The specific codes that will be discussed at the meeting will be identified on the CMS Internet

website at *www.hcfa.gov/audience/planprov.htm* by June 26, 2002.

New DME: This meeting is open to the general public. The on-site check-in for visitors who have registered to attend the meeting will be held from 7:30 a.m. to 8 a.m., followed by opening remarks. The purpose of the open meeting is to allow the public an opportunity, in a public forum, to do the following:

- Present to CMS representatives information and recommendations regarding the coding requests listed on the agenda.
- Discuss with representatives of the HCPCS Workgroup its preliminary recommendation regarding these coding requests.
- Discuss preliminary recommendations of CMS regarding payment for new DME items.

For each item on the agenda, the discussion will begin with CMS's presenting an overview of the request and the factors we considered in reaching our preliminary recommendations. Following the CMS overview, the entity that requested the HCPCS coding change will be given a maximum of 15 minutes to make a public presentation concerning its coding change application and payment for the item. For a requestor to participate in the public meeting as a primary presenter, the requestor must be registered with the HCPCS Coordinator, Kaye Riley, (410) 786–5323. For purposes of registering as a primary presenter, you must, at least 15 days prior to the meeting, submit the following to the HCPCS coordinator:

- A brief statement, one to two pages, of the general nature of the information you plan to present.
- The names and addresses of the proposed presenters.
- An estimate of the time required to make the presentation.

Primary presenters will be given up to 15 minutes for their presentations. Other presenters will be permitted to sign up at the meeting on a first come basis to make 5-minute presentations on agenda items. Time constraints will determine how many presenters, besides the primary presenter, will be allowed to make a public presentation. Speakers following the primary presenters will also be required to submit on the day of the meeting a one to two-page summary of their presentation. Other persons in attendance, who do not have the opportunity to make a presentation, may, at the meeting, submit their comments in a written statement of one to two typed pages.

We will request that speakers declare at the meeting and in any written statements whether or not they have any financial involvement with manufacturers of any items or services being discussed (or with their competitors). This would include any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer. A summary of each meeting will be posted on the HCPCS website within 3 weeks following the meeting. The HCPCS website is *http://www.hcfa.gov/medicare/hcpcs.htm.*

The DME public meetings will be held in the main auditorium at CMS's Central Office, located at 7500 Security Boulevard, Baltimore, MD, 21244. The first meeting is scheduled for March 11, 2002. For the remainder of 2002, meetings are also scheduled for May 13 and June 17. The meetings will begin at 8 a.m., E.S.T. For a coding request to be included on the agenda for the May or June meeting, it must received by April 1. For a coding request to be included on the agenda for the March meeting, it must be received at least 45 days before the scheduled date of the March meeting. If a coding request does not meet this deadline, it will be placed on the agenda for the next meeting.

The agenda for an upcoming DME public meeting will be posted on the HCPCS website at least 30 days before the scheduled date for the meeting. Posted with the agenda, there will also be a fact sheet, as described above, for each coding request to be reviewed at the meeting.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 19, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–29326 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 7, 2001, from 8 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776 or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long, from 9 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: On December 7, 2001, from 8 a.m. to 9 a.m., the meeting will open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 17, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 17, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the December 7, 2001, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Closed Committee Deliberations: On December 7, 2001, from 9 a.m. to 5 p.m., the meeting will be closed to permit

discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act 5 U.S.C. app. 2).

Dated: November 15, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–29225 Filed 11–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 13, 2001, from 8 a.m. to 5:30 p.m. and on December 14, 2001, from 8 a.m. to 3:30 p.m.

Location: Hilton Silver Spring Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 2001, the following committee updates are tentatively scheduled: Transmissible spongiform encephalopathies (TSE) guidance, Centers for Disease Control and Prevention workshop on factor VIII, update on disaster response, and compliance quality control oversight. In the morning, the committee will hear presentations, discuss and make recommendations on potential concerns for simian foamy virus (SFV) transmission by blood and blood products. In the afternoon, the committee will hear presentations, discuss and make recommendations on the leukocyte reduction guidance. On December 14, 2001, the committee will hear presentations and discuss and make recommendations on human cells, tissues and cellular and tissue-based products: Risk factors for semen donation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 3, 2001. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m., and between approximately 3:45 p.m. and 4:45 p.m. on December 13, 2001; and between approximately 11:30 a.m. and 1 p.m. on December 14, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–29226 Filed 11–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Service Administration

Community Mental Health Services and Substance Abuse Prevention and Treatment Block Grant Maintenance of Effort Requirements: Exclusion from Future Year Calculations

In keeping with SAMHSA's delegation of authority from the Secretary for Health and Human Services (HHS) and in compliance with section 1915(b)(2) and section 1930(b) of the Public Health Service (PHS) Act as amended by Public Law 106–310, the Substance Abuse and Mental Health Services Administration published a guidance in the **Federal Register** (66 FR 35658) on July 6, 2001, to be used in determining whether to approve the exclusion of certain expenditures from aggregate expenditures used by the State in calculating the maintenance of effort requirement under the Community Mental Health Services (CMHS) Block Grant program and/or the Substance Abuse Prevention and Treatment (SAPT) Block Grant program.

In implementing the guidance, SAMHSA has learned that there was an unintendedly harsh consequence as a result of our stating that the funds to be excluded had to be appropriated by the State after the date of enactment of Public Law 106–310, October 17, 2000, which contained the new authority permitting the exclusion of certain expenditures. The intention of the requirement was to ensure that the new statutory authority was not applied retroactively, contrary to our understanding of the intent of the provision. In using the term ''appropriated,'' however, the agency inadvertently also eliminated consideration of funds that were appropriated by those States whose fiscal year 2001 began before October 17, 2000, the date of enactment of Public Law 106–310, thus creating an inequitable situation. Changing the language of the guidance to the date of expenditure rather than appropriation addresses both the issue of retroactive application and equitability.

Accordingly, we are revising the guidance by substituting in the second element of the guidance the word ''expended'' for the word ''appropriated.'' Thus funds that were appropriated by the State prior to October 17, 2000 but had not yet been expended may, in the discretion of the Administrator of SAMHSA, be considered for an exclusion.

Thus the guidance is now as follows:

''In order for SAMHSA to approve a request from a State to have excluded from the aggregate State expenditures funds appropriated by the State legislature to the principal agency for authorized activities which are of a non-recurring nature and for a specific purpose, the following is necessary:

1. The State shall request the exclusion separately from the application;

2. The request shall be signed by the State's Chief Executive Officer or by an individual authorized to apply for the SAPT or CMHS Block Grant on behalf of the Chief Executive Officer. SAMHSA will consider such requests for funds expended after the date of enactment of Public Law 106–310, October 17, 2000, in the first year for which additional funds are being added to the budget for such activities;

3. The State shall provide documentation that supports its position that the funds were appropriated by the State legislature for authorized activities which are of a non-recurring nature and for a specific

purpose, indicates the length of time the project is expected to last in years and months, and affirms that these expenditures would be in addition to funds needed to otherwise meet the State's maintenance of effort requirement for the year for which it is applying for exclusion; and

4. The Administrator of SAMHSA agrees that the criteria for exclusion have been met.

Nothing in this guidance limits a State from requesting more than one exclusion in any one year. If during a particular year the State wishes to submit more than one project for exclusion, it should do so in a single request.''

Dated: November 16, 2001.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Administration.

[FR Doc. 01–29217 Filed 11–21–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4564–N–06]

Notice of Proposed Information Collection: Evaluation Study of Rounds 3–5 of HUD's Lead Hazard Control Grant Program

AGENCY: Office of Healthy Homes and Lead Hazard Control, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 7, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Gail N. Ward, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room P3206, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Dr. Peter Ashley, 202–755–1785 ext. 115 (this is not a toll-free number) for available documents regarding this proposal.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The Notice also lists the following information:

Title of Proposal: Evaluation Study of Rounds 3–5 of HUD's Lead Hazard Control Grant Program.

OMB Control Number: To be assigned.

Need for the Information and Proposed Use: In order to assist in fulfilling its mission of eliminating lead-based paint hazards and other housing-related threats to children's health and safety in low-income privately-owned homes, HUD's Office of Healthy Homes and Lead Hazard Control operates a grant program for State and local governments to develop and implement cost-effective methods for the inspection and reduction of lead-based paint hazards in private owner-occupied and rental housing for low and moderate income families. From 1995 through 1998, HUD initiated Rounds 3–5 of this Lead Hazard Control Grant Program, awarding grants to 73 different States and localities. The purpose of this information collection is to study the effectiveness of the lead hazard control treatments that these recipient programs administered under the HUD grants, at specified time points (e.g., from 1 to 4 years) after the treatments were administered. To do this, HUD will study selected housing units that received lead hazard control treatments within approximately ten programs that received grants in Rounds 3–5 of this program. In housing units that agree to participate in the study, researchers will collect household information, will visually inspect the integrity of the applied treatments, and will collect environmental samples (e.g., dust and soil) to be analyzed for lead content. The data will be combined with similar types of ''baseline'' data for the same housing units that the grant programs collected prior to administering the treatments in these units. The pre-treatment data will be obtained for this evaluation directly from the grant programs with their cooperation. The data collected during this Rounds 3–5 Evaluation Project should allow HUD to assess how post-treatment dust-lead levels, or changes in dust-lead levels between post-treatment and pre-treatment, may differ between housing units administered treatments of different intensity or cost. The data will also contribute to HUD's awareness of long-term performance of selected lead hazard control treatments.

For a participating housing unit, this information will involve: (1) A brief interior and exterior visual inspection to assess housing conditions and the integrity of the applied treatments; (2) collection of dust-wipe samples (from floors, window sills, window troughs, selected wall surfaces, and selected exterior surfaces) and soil samples for lead analysis; and (3) a brief visual survey of the immediate neighborhood to identify and record potential releases of lead in the neighborhood environment. At least one, but possibly two, information collection visits will be made to participating housing units over a two- to three-year period. If appropriate, the results of this information collection will be used to improve existing HUD guidance for cost-effective and safe lead hazard control treatments.

Agency Form Numbers: None.

Members of affected public: Selected property owners and residents of housing units that agree to participate in the study representing approximately ten state-, county-, or city-level lead hazard control grant programs across the United States.

Total Burden Estimate:

Number of Respondents: 600.

Frequency of Response: maximum of 2.

Total hours of Response: 4,050.

TABLE 1.—CALCULATION OF RESPONDENT BURDEN OVER THE FULL STUDY PERIOD

Burden-causing task	Burden to tenants or resident property owners
Undergo recruitment and be briefed on the study.	15 minutes.
Review and complete Informed Consent form.	15 minutes.
Provide access to researchers for conducting post-treatment surveys and environmental sampling.	3 hours in each of 2 visits.

TABLE 1.—CALCULATION OF RESPONDENT BURDEN OVER THE FULL STUDY PERIOD—Continued

Burden-causing task	Burden to tenants or resident property owners
Undergo any post-study briefing.	15 minutes.
Total	6.75 hours.

Average Response Time: 6.75 hours (assuming 2 visits for conducting surveys and sampling).

Total Burden for 600 units: 4,050 hours.

Status of the Proposed Information Collection: New collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended. Dated: June 14, 1999.

Dated: November 15, 2001.

David E. Jacobs,

Director, Office of Healthy Homes and Lead Hazard Control.

[FR Doc. 01–29269 Filed 11–21–01; 8:45 am]

BILLING CODE 4210–70–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–47]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: November 23, 2001.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 15, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 01–29011 Filed 11–21–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Reopening of Public Comment on Draft Recovery Goals for Four Endangered Fishes of the Colorado River Basin

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of reopening of public comment.

SUMMARY: The Fish and Wildlife Service (Service) provides notice of the reopening of the public comment period on the Draft Recovery Goals for the Four Endangered Fishes of the Colorado River Basin. The initial public comment period opened September 10, 2001, and closed October 25, 2001. To accommodate several requests for extension, the Service is reopening the comment period for an additional 15 days. Copies of the Draft Recovery Goals are available (in *.pdf format) for viewing and downloading at: *http://www.r6.fws.gov/crrip/rg.htm,* or from the Upper Colorado River Endangered Fish Recovery Program (see **ADDRESSES** section). The Service is seeking comments or suggestions from the public, other concerned government agencies, the scientific community, or any other interested parties concerning the Draft Recovery Goals. Make requests and mail comments to the Director at the address below. Comments already submitted on the Draft Recovery Goals need not be resubmitted as they will be fully considered.

DATES: The reopen comment period closes December 10, 2001.

ADDRESSES: Written comments and materials concerning this proposal should be sent to Dr. Robert Muth, Director, Upper Colorado Endangered Fish Recovery Program, U.S. Fish and Wildlife Service, Post Office Box 25486, DFC, Denver, Colorado, 80225. You may submit comments by sending electronic mail (e-mail) to: *colorivgoals@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Robert Muth, Director (extension 268), Dr. Thomas Czapla (extension 228) or Debbie Felker (extension 227), Coordinators (see **ADDRESSES** above), at telephone (303) 969–7322.

SUPPLEMENTARY INFORMATION: To further the recovery of humpback chub (*Gila cypha*), bonytail (*Gila elegans*), Colorado pikeminnow (formerly named Colorado squawfish; *Ptchocheilus lucius*), and razorback sucker (*Xyrauchen texanus*), the Service announced on September 10, 2001, the availability of the Draft Recovery Goals for these endangered fishes of the Colorado River Basin and a 45-day comment period. These goals will serve as a supplement and amendment to the respective recovery plans for each species. We solicit review and comments from agencies and the public on these Draft Recovery Goals.

The purpose of these supplements and amendments are to describe site-specific management actions/tasks needed to minimize or remove threats; provide objective, measurable recovery criteria for downlisting and delisting that identify levels of demongraphic and genetic viability needed for self-sustaining populations; and provide estimates of the time required to achieve recovery of each of the four endangered fish species. Downlisting and delisting criteria by listing factors and management actions, as well as demographic criteria, are presented for populations of each species within recovery units. In addition, updated life-history information and statistical criteria for monitoring are identified. The recovery goals for the humpback chub, razorback sucker and bonytail are identified by two recovery units, upper basin (above Glen Canyon Dam, Arizona) and lower basin. Recovery of the Colorado pikeminnow is currently considered only for the upper basin.

Authority: The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

John A. Blankenship,

Deputy Regional Director, Denver, Colorado.

[FR Doc. 01–29220 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of a Permit Application (Bartlett) for Incidental Take of the Houston Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Virginia Bartlett (Applicant) has applied for an incidental take

permit (TE–049034–0) pursuant to section 10(a) of the Endangered Species Act (Act). The requested permit would authorize the incidental take of the endangered Houston toad. The proposed take would occur as a result of the construction and occupation of a single-family residence on approximately 0.75 acres of a 33.525-acre property on FM 2104, Bastrop County, Texas.

DATES: Written comments on the application should be received on or before December 24, 2001.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, PO Box 1306, Room 4102, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Clayton Napier, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0057). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCP should be submitted to the Supervisor, U.S. Fish and Wildlife Service, Austin, Texas, at the above address. Please refer to permit number TE–049034–0 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Clayton Napier at the above U.S. Fish and Wildlife Service, Austin Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the ''taking'' of endangered species such as the Houston toad. However, the Fish and Wildlife Service (Service), under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

An Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take application has been prepared. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made until at least 30 days from the date of publication of this notice. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

Applicant: Virginia Bartlett plans to construct a single-family residence, within 7 years, on approximately 0.75 acres of a 33.525-acre property on FM 2104, Bastrop County, Texas. This action will eliminate 0.75 acres or less of Houston toad habitat and result in indirect impacts within the lot. The Applicant proposes to compensate for this incidental take of the Houston toad by providing $3,000.00 to the Houston Toad Conservation Fund at the National Fish and Wildlife Foundation for the specific purpose of land acquisition and management within Houston toad habitat.

Steven M. Chambers,

Acting Regional Director, Region 2.

[FR Doc. 01–29182 Filed 11–21–01; 8:45 am]

BILLING CODE 4510–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–680–02–1610–JP–064B]

Temporary Motorized Vehicle use Closure and Establish an Interim Motorized Vehicle Access Network on Selected Federal Lands in Western San Bernardino County, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure to motorized vehicle use on selected federal lands in San Bernardino County, California and establish an interim motorized vehicle access network. The area encompasses 222,750 acres in the Fremont subregion.

DATES: The temporary closure was approved November 15, 2001, and is in effect.

ADDRESSES: Bureau of Land Management, Barstow Field Office, 2601 Barstow Rd, Barstow, CA 92311.

FOR FURTHER INFORMATION CONTACT: Tim Read, BLM, Barstow Field Office 2601 Barstow Rd, Barstow, CA 92311 , telephone (760) 252–6000. The closure is posted in the Barstow Field Office and at places near and/or within the area to which the closure applies. Maps identifying the affected areas are available at the Barstow Field Office as well as on the Bureau of Land Management (BLM) California website at *www.ca.blm.gov.*

SUPPLEMENTARY INFORMATION: This temporary closure is implemented pursuant to Title 43 Code of Federal Regulations (CFR) 8341.2(a). The closure was approved November 15, 2001 and will remain in effect until a Record of Decision is signed on the West Mojave Coordinated Management Plan (WEMO Plan), which is expected to be signed June 2003.

Exceptions to this closure include government vehicles conducting official business which shall be allowed inside the closed areas as authorized and an interim route network signed as open routes on the ground and identified on the map. Official business may include public service emergencies, resource monitoring/research, and management activities, and other actions authorized by BLM's Barstow Field Office.

Dated: November 15, 2001.

Tim Read,

Field Manager.

[FR Doc. 01–29346 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–610–01–1220–AA]

Meeting of the California Desert District Advisory Council

SUMMARY: Notice is hereby given, in accordance with Public Laws 92–463 and 94–579, that the California Desert District Advisory Council to the Bureau of Land Management, U.S. Department of the Interior, will participate in a field tour of the BLM-administered public lands on Friday, December 7, 2001, from 7:30 a.m to 5:30 p.m., and meet in formal session on Saturday, December 8, from 8 a.m. to 5 p.m. The Saturday meeting will be held at the Southwest Performing Arts Theatre, Southwest High School, located at 2001 Ocotillo Drive, El Centro, California. The Bureau of Land Management is publishing this notice without 15 days public notice in order to avoid any additional delays.

The Council and interested members of the public will assemble for a field tour at the parking lot of the Best Western John Jay Inn at 7:15 a.m. and depart 7:30 a.m. The Inn is located at 2352 S. 4th Street, El Centro. Tour stops will include areas within the Northern and Eastern Colorado Desert Coordinated Management planning area and the Imperial Sand Dunes Recreation Area. Presentations and discussions will focus on issues being addressed in the Draft Northern and Eastern Colorado Desert Coordinated Management Plan and Draft Northern and Eastern Mojave Plan, and development of the Draft Imperial Sand Dunes Recreation Area Resource Management Plan. The public is welcome to participate in the tour, but should plan on providing their own transportation, drinks, and lunch.

Agenda items for the Saturday Council meeting will include presentations and Council discussions regarding the Draft Northern and Eastern Colorado Desert Coordinated Management Plan and the Draft Northern and Eastern Mojave Plan, and a summary of public comments for the

two draft plans, which closed November 1, 2001. The Council also will be briefed on the status of the development of the Draft Imperial Sand Dunes Recreation Area Resource Management Plan.

All Desert District Advisory Council meetings are open to the public. Time for public comment may be made available by the Council Chairman during the presentation of various agenda items, and is scheduled at the end of the meeting for topics not on the agenda.

Written comments may be filed in advance of the meeting for the California Desert District Advisory Council, c/o Bureau of Land Management, Public Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507–0714. Written comments also are accepted at the time of the meeting and, if copies are provided to the recorder, will be incorporated into the minutes.

FOR FURTHER INFORMATION CONTACT: Doran Sanchez, BLM California Desert District Public Affairs Specialist, (909) 697–5220.

Dated: November 8, 2001.

Tim Salt,

District Manager.

[FR Doc. 01–29345 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

(AZ–910–0777–26–241A)

State of Arizona Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Arizona Resource Advisory Council Meeting notice.

SUMMARY: This notice announces a meeting of the Arizona Resource Advisory Council (RAC). The meeting will be held on December 6, in Phoenix, Arizona. The meeting will be held at the BLM National Training Center, 9828 North 31st Avenue, Phoenix, Arizona. It will begin at 9:00 a.m and will conclude at approximately 4:00 p.m. The Bureau of Land Management is publishing this notice without 15 days public notice in order to avoid any additional delays. The agenda items to be covered include review of the July 23–24, 2001, meeting minutes; New RAC Member Introductions; BLM State Director's Update on legislation, regulations and statewide planning efforts; Briefing on the Programmatic Environmental Impact Statement on Conservation and Restoration Treatments; Updates on the National Off-Highway Vehicle Strategy, Draft Las Cienegas Resource Management Plan and Environmental Impact Statement; and Statewide Planning Schedule; RAC Discussion on National Landscape Conservation System Strategy; Update Proposed Field Office Rangeland Resource Teams; Reports from BLM Field Office Managers; Reports by the Standards and Guidelines, Recreation and Public Relations, Wild Horse and Burro Working Groups; Reports from RAC members; and Discussion of future meetings. A public comment period will be provided at 11:30 a.m. on December 6, 2001, for any interested publics who wish to address the Council.

FOR FURTHER INFORMATION CONTACT: Deborah Stevens, Bureau of Land Management, Arizona State Office, 222 North Central Avenue, Phoenix, Arizona 85004–2203, (602) 417–9215.

Carl Rountree,

Arizona Associate State Director.

[FR Doc. 01–29347 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

National Park Service

Padre Island National Seashore, Corpus Christi, Texas

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of a plan of operations, environmental assessment, and a floodplain statement of findings for a 30-day public review at Padre Island National Seashore, Kleberg and Kenedy Counties, Texas.

SUMMARY: The National Park Service (NPS), in accordance with section 9.52(b) of Title 36 of the Code of Federal Regulations and Executive Order 11988, Floodplain Management, has received from BNP Petroleum Corporation a Plan of Operations for drilling and production of the Dunn-Murdock #1 well from a surface location north of the Yarborough Pass Road within Padre Island National Seashore. Additionally, the NPS has prepared an Environmental Assessment and a Floodplain Statement of Findings for the site of the proposed well.

DATES: The above documents are available for public review and comment on or before December 24, 2001.

ADDRESSES: The Plan of Operations, Environmental Assessment, and Floodplain Statement of Findings are available for public review and comment in the Office of the Superintendent, Padre Island National Seashore, 20301 Park Road 22, Corpus Christi, Texas. Copies of the Plan of Operations are available, for a duplication fee, from the Superintendent, Padre Island National Seashore, PO Box 181300, Corpus Christi, Texas 78480–1300.

FOR FURTHER INFORMATION CONTACT: Arlene Wimer, Environmental Protection Specialist, Padre Island National Seashore, PO Box 181300, Corpus Christi, Texas 78480–1300, Telephone: 361–949–8173 x 224, e-mail at *Arlene_Wimer@nps.gov.*

SUPPLEMENTARY INFORMATION: If you wish to submit comments about this document within the 30 days; mail them to the post office address provided above, hand-deliver them to the park at the street address provided above, or electronically file them to the e-mail address provided above. Our practice is to make comments, including names and home addresses of responders, available for public review during regular business hours.

Dated: October 26, 2001.

Luis J. Gonzales,

Acting Superintendent, Padre Island National Seashore.

[FR Doc. 01–29176 Filed 11–21–01; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Extension of a currently approved collection; Controlled Substances Import/Export Declaration—DEA Form 236.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 66, Number 201, page 52780 on September 19, 2001, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This

process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Controlled Substances Import/Export Declaration—DEA Form 236.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: DEA–236. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. Other: None. DEA–236 provides the DEA with control measures over the importation and exportation of controlled substances as required by both domestic and international drug control laws. Affected public consists of businesses or other for profit organizations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 358 respondents with an average 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,432 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29289 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Extension of a currently approved collection; Import/Export Declaration: Precursor and Essential Chemicals—DEA Form 486.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** at Volume 66, Number 182, page 48275 on September, 2001, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this Information Collection

(1) Type of information collection: Extension of a currently approved collection.

(2) The title of the form/collection: Import/Export Declaration: Precursor and Essential Chemicals.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.: DEA–486. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Other: Individuals or households. The Chemical Diversion and Trafficking Act of 1988 requires those who import/export certain chemicals to notify the DEA 15 days prior to shipment. Information will be used to prevent shipments not intended for legitimate purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: DEA Form 486: 550 respondents with an average 12 minutes per response. DEA Quarterly Report: 100 respondents with an average 30 minutes per response.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA Form 486: 1,400 annual burden hours. DEA Quarterly Report: 200 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW, Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29290 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-day notice of information collection under review: extension of a currently approved collection; application for registration Under Domestic Chemical Diversion Control Act of 1993 and renewal application for registration under Domestic Chemical Control Act of 1993.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 66, Number 182, page 48276 on September 19, 2001, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202)–395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Application for Registration Under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form No.: DEA–510 and DEA–510a. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: Individuals or households. The Domestic Chemical Diversion Control Act requires that distributors, importers, and exporters of listed chemicals which are being diverted in the United States for the production of illicit drugs must register with DEA. Registration provides a system to aid in the tracking of the distribution of List I chemicals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 3,200 respondents with an average 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,600 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29291 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Extension of a currently approved collection; Report of theft or loss of controlled substances—DEA Form 106.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 66, Number 182, pages 48272–48273 on September 19, 2001, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including

whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Report of Theft or Loss of Controlled Substances—DEA Form 106.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.:* DEA–106. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. *Other:* Individuals or households. Title 21 CFR, 1301.74(c) and 1301.76(b) requires DEA registrants to complete and submit a DEA–106 upon discovery of a theft or loss of controlled substances. *Purpose:* accurate accountability; monitor substances diverted into illicit markets and develop leads for criminal investigations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 3,765 respondents with an average 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,076 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29286 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under review: Extension of a Currently Approved Collection; Application for Permit to Export Controlled Substances—DEA Form 161.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on September 19, 2001 (66 FR 48273), allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202)–395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of reports.

Overview of this information collection:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Application for Permit to Export Controlled Substances—DEA Form 161.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.:* DEA–161. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. *Other:* None. Title 21 CFR section 1312.22 requires individuals who export controlled substances in schedules I and II to obtain a permit from DEA. Information is used to issue export permits and exercise control over exportation of controlled substances and compile data for submission to UN for treaty requirements.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/rely:* 225 respondents with an average 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,000 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29287 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Extension of a currently approved collection;

Registrants Inventory of Drugs Surrendered—DEA Form 41.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), has submitted the following information collection request to the Office of Management and Budget OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 66, Number 182, page 48274 on September, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until December 24, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Registrants Inventory of Drugs Surrendered—DEA 41.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.:* DEA–41. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. *Other:* None. Title 21, CFR, 1307.21 requires that any registrant desiring to voluntarily dispose of controlled substances shall list these controlled substances on DEA Form 41 and submit to the nearest DEA office. The DEA 41 is used to account for surrendered destroyed controlled substances, and its use is mandatory.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 20,000 respondents with an average 30 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 10,000 annual burden hours.

DEA wishes to note that the language of the DEA Form 41 is being changed to reflect DEA policy that controlled substances are no longer accepted by DEA field offices for destruction. Inquiries regarding destruction of controlled substances may be made to DEA field offices.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management, Division United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20004.

Dated: November 19, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–29288 Filed 11–21–01; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register,** or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing

Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department.

Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Withdrawn General Wage Determination Decisions

This to advise all interested parties that the Department of Labor is withdrawing, from the date of this notice, General Wage Determination Nos. CA10019, CA010023 and CA10025. See CA010013.

Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c) (2) (i) (A), when the opening of bids is less than ten (10) days from the date of this notice, this action shall be effective unless the agency finds that there is insufficient time to notify bidders of the change and the finding is documented in the contract file.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

VOLUME I:

Connecticut
CT010001 (Mar. 02, 2001)
CT010003 (Mar. 02, 2001)
CT010004 (Mar. 02, 2001)
CT010005 (Mar. 02, 2001)
CT010008 (Mar. 02, 2001)
Massachusetts
MA010001 (Mar. 02, 2001)
MA100007 (Mar. 02, 2001)
New York
NY010007 (Mar. 02, 2001)

VOLUME II:

Maryland
MD010010 (Mar. 02, 2001)
MD010036 (Mar. 02, 2001)
MD010045 (Mar. 02, 2001)
MD010046 (Mar. 02, 2001)
MD010048 (Mar. 02, 2001)
MD010056 (Mar. 02, 2001)
MD010057 (Mar. 02, 2001)
Pennsylvania
PA010005 (Mar. 02, 2001)
PA010025 (Mar. 02, 2001)
Virginia
VA010005 (Mar. 02, 2001)
VA010014 (Mar. 02, 2001)
VA010015 (Mar. 02, 2001)
VA010022 (Mar. 02, 2001)
VA010023 (Mar. 02, 2001)
VA010025 (Mar. 02, 2001)
VA010031 (Mar. 02, 2001)
VA010033 (Mar. 02, 2001)
VA010052 (Mar. 02, 2001)
VA010057 (Mar. 02, 2001)
VA010058 (Mar. 02, 2001)
VA010067 (Mar. 02, 2001)
VA010076 (Mar. 02, 2001)
VA010078 (Mar. 02, 2001)
VA010079 (Mar. 02, 2001)
VA010085 (Mar. 02, 2001)
VA010087 (Mar. 02, 2001)
VA010088 (Mar. 02, 2001)
VA010092 (Mar. 02, 2001)
VA010099 (Mar. 02, 2001)

VOLUME III:

Florida
FL010001 (Mar. 02, 2001)
FL010009 (Mar. 02, 2001)
Georgia
GA010053 (Mar. 02, 2001)

VOLUME IV:

Illinois
IL010002 (Mar. 02, 2001)
IL010008 (Mar. 02, 2001)
IL010009 (Mar. 02, 2001)
IL010011 (Mar. 02, 2001)
IL010013 (Mar. 02, 2001)
IL010015 (Mar. 02, 2001)
IL010016 (Mar. 02, 2001)
IL010021 (Mar. 02, 2001)
IL010022 (Mar. 02, 2001)
IL010024 (Mar. 02, 2001)
IL010027 (Mar. 02, 2001)
IL010028 (Mar. 02, 2001)
IL010031 (Mar. 02, 2001)
IL010032 (Mar. 02, 2001)
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IL010034 (Mar. 02, 2001)
IL010036 (Mar. 02, 2001)
IL010037 (Mar. 02, 2001)
IL010044 (Mar. 02, 2001)
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IL010050 (Mar. 02, 2001)
IL010051 (Mar. 02, 2001)
IL010056 (Mar. 02, 2001)
IL010058 (Mar. 02, 2001)
IL010060 (Mar. 02, 2001)
IL010062 (Mar. 02, 2001)
IL010063 (Mar. 02, 2001)
Illinois
IL010064 (Mar. 02, 2001)
IL010066 (Mar. 02, 2001)
IL010067 (Mar. 02, 2001)
IL010068 (Mar. 02, 2001)
IL010070 (Mar. 02, 2001)
Michigan
MI010001 (Mar. 02, 2001)
MI010003 (Mar. 02, 2001)
MI010005 (Mar. 02, 2001)
MI010019 (Mar. 02, 2001)
MI010031 (Mar. 02, 2001)
MI010040 (Mar. 02, 2001)
MI010066 (Mar. 02, 2001)
MI010067 (Mar. 02, 2001)
MI010068 (Mar. 02, 2001)
MI010069 (Mar. 02, 2001)
MI010070 (Mar. 02, 2001)
MI010073 (Mar. 02, 2001)
MI010077 (Mar. 02, 2001)
MI010099 (Mar. 02, 2001)
MI010100 (Mar. 02, 2001)
MI010101 (Mar. 02, 2001)
MI010105 (Mar. 02, 2001)

VOLUME V:

Nebraska
NE010009 (Mar. 02, 2001)
NE010011 (Mar. 02, 2001)
Oklahoma
OK010031 (Mar. 02, 2001)
OK010032 (Mar. 02, 2001)
Texas
TX010014 (Mar. 02, 2001)
TX010069 (Mar. 02, 2001)

VOLUME VI:

Idaho
ID010003 (Mar. 02, 2001)

VOLUME VII:

California
CA010013 (Mar. 02, 2001)
CA010028 (Mar. 02, 2001)
CA010030 (Mar. 02, 2001)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage'' determinations Issued Under the Davis-Bacon And Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National

Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 15th day of November 2001.

Terry Sullivan,

Acting Chief, Branch of, Construction Wage, Determinations.

[FR Doc. 01–29139 Filed 11–21–01; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Advisory Committee on Construction Safety and Health; Notice of Open Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of a meeting of the Advisory Committee on Construction Safety and Health (ACCSH).

SUMMARY: OSHA is notifying the public that the Advisory Committee on Construction Safety and Health (ACCSH) will meet December 6, 2001, in Washington, DC. This meeting is open to the public.

DATES, TIMES, LOCATION: ACCSH will meet from 8 a.m. to 5 p.m., Thursday, December 6, at the Marriott Hotel, 1331 Pennsylvania Ave., NW., Washington, DC. ACCSH work groups will meet December 4–5 at the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC. For further information on meetings of ACCSH work groups, please refer to the OSHA Web site at *http:/www.osha.gov* or contact Jim Boom at OSHA's Directorate of Construction, telephone (202) 693–1839.

FOR FURTHER INFORMATION CONTACT: Veneta Chatmon, OSHA Office of Public Affairs, Room N–3647, 200 Constitution Ave., NW, Washington, DC 20210, telephone (202) 693–1999.

SUPPLEMENTARY INFORMATION: ACCSH will meet December 6, 2001, in Washington, DC. This meeting is open to the public. The agenda for this meeting includes:

- Remarks by the Assistant Secretary for the Occupational Safety and Health Administration, John L. Henshaw
- Special Presentation—National Institute for Occupational Safety and Health
- ACCSH Work Group updates
- OSHA Training Institute—Distance Learning
- Tower Erection—Update on North Carolina's Initiatives
- World Trade Center—Update
- Directorate of Construction report

An official record of the meeting will be available for public inspection at the OSHA Docket Office, Room N–2625, at the address above, telephone (202)–693–2350. All ACCSH meetings and those of its work groups are open to the public. Individuals needing special accommodation should contact Veneta Chatmon no later than November 30, 2001, at the above address.

Interested parties may submit written data, views or comments, preferably with 20 copies, to Veneta Chatmon, at the address listed above. OSHA will provide submissions received prior to the meeting to ACCSH members and will include each submission in the record of the meeting.

Attendees may also request to make an oral presentation by notifying Veneta Chatmon before the meeting. The request must state the amount of time desired, the interest represented by the presenter (e.g., the names of the business, trade association, government Agency) if any, and a brief outline of the presentation. The Chair of ACCSH may grant the request at his discretion and as time permits.

The following ACCSH works groups will meet in the Francis Perkins Building:

- Supart N—Cranes—8 a.m. to 5 p.m., Tuesday, December 4 in room N–4437 A&B and 8 a.m. to 5 p.m., Wednesday, December 5 in room S–4215 A&B.

For further information on meetings of ACCSH works groups, please refer to the OSHA Web site at *http://www.osha.gov* or contact Jim Boom at the telephone number listed above.

Authority: John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice under the authority granted by section 7 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333), and Secretary of Labor's Order No. 6–96 (62 FR 181).

Signed at Washington, DC on November 15, 2001.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 01–29180 Filed 11–21–01; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. NRTL2–2001]

TUV America, Inc., Application for Recognition

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of TUV America, Inc., for recognition as a Nationally Recognized Testing Laboratory (NRTL) under 29 CFR 1910.7, and presents the Agency's preliminary finding. This preliminary finding does not constitute an interim or temporary approval of this application.

DATES: Comments submitted by interested parties, or any request for extension of the time to comment, must be received no later than December 24, 2001.

ADDRESSES: Submit written comments concerning this notice to: Docket Office, Docket NRTL2–2001, U.S. Department of Labor, Occupational Safety and Health Administration, Room N2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693–1648. Submit requests for extension concerning this notice to: Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3653, 200 Constitution Avenue, NW, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Bernard Pasquet, Office of Technical Programs and Coordination Activities, NRTL Program, Room N3653 at the above address, or phone (202) 693–2110.

SUPPLEMENTARY INFORMATION:

Notice of Application

The Occupational Safety and Health Administration (OSHA) hereby gives notice that TUV America, Inc. (TUVAM), has applied for recognition as a Nationally Recognized Testing Laboratory (NRTL). The scope of this recognition would include testing and certification of the equipment or materials (i.e., products), and include the sites, described later in this notice. TUVAM also seeks to use the supplemental programs also described later herein. The applicant's NRTL activities will be handled by its TUV Product Services division.

OSHA recognition of an NRTL signifies that the organization has met the legal requirements in § 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products ''properly certified'' by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications by an NRTL for initial recognition or for expansion or renewal of this recognition following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. We maintain an informational web page for each NRTL, which details its scope of recognition. These pages can be accessed from our web site at *http://www.osha-slc.gov/dts/otpca/nrtl/index.html*.

The current address of the facilities (sites) covered by this application are: TUV Product Services (TUVAM), 5 Cherry Hill Drive, Danvers, Massachusetts 01923, TUV Product Services (TUVAM), 10040 Mesa Rim Road, San Diego, California 92121, TUV Product Services (TUVAM), 1775 Old Highway 8 NW, Suite 104, New Brighton (Minneapolis), Minnesota 55112.

Background

According to the application, TUV America, Inc., is a ''privately held Massachusetts'' corporation. At time of application, the applicant was TUV Product Services, Inc., a wholly-owned subsidiary of TUVAM and also a ''privately held Massachusetts'' corporation, according to the application. However, TUVAM informed OSHA recently that TUV Product Services, Inc. (TPS), no longer exists as a separate legal entity but is now a division within TUVAM. As stated above, this division would handle TUVAM's NRTL activities. As a result, OSHA has primarily evaluated the testing and certification capabilities of this division and former separate entity.

The application states that TUV Product Services, Inc., was incorporated in 1990, and that it has ''10 years of experience with [testing] medical, telecommunications, computing, industrial machinery and controls, software, consumer electronics, sporting, and appliance products.'' The applicant submitted information that traces its origins to German steam boiler inspection associations founded in the 1870's ''to help regulate and supervise the safety of steam installations in the interest of public safety.'' TUV Product Services GmbH (TUVPSG), which is organizationally part of TUVAM's parent company, included similar information in its application for recognition. OSHA has already processed TUVPSG's application and granted it recognition on July 20, 2001 (see **Federal Register** notice: 66 FR 38032).

Although TUVAM and TUVPSG are affiliated, they have separate operations and are legally distinct, and their recognition would be separate. However, by their own arrangement, both organizations would utilize the same registered certification mark for purposes of their NRTL certifications. OSHA imposed a condition on TUVPSG regarding use of this mark and would impose a related condition on TUVAM, as described later in this notice.

The application showed that TUVAM was owned by TUV Suddeutschland and TUV Nord, both based in Germany. However, as mentioned in the March 16 notice for TUVPSG, recently TUV Suddeutschland became sole owner of TUVAM. Also, it provides testing and other technical services in a number of areas throughout the world. The on-site review report (see Exhibit 3) indicates that TUVAM ''receives administrative and technical direction'' from TUVPSG. Moreover, the report indicates that TUVAM owns and its TPS division operates laboratories at additional U.S. locations, i.e., sites not listed above. The application only covers the three sites listed above, of which the Danvers site is currently TUVAM's headquarters.

TPS and therefore TUVAM submitted an application for recognition, dated February 1, 1999 (see Exhibit 2). In response to a request from OSHA for clarification and additional information, TUVAM supplemented its application in a submission dated November 9, 1999 (see Exhibit 2–1). In addition, the applicant provided additional documents on April 28 and May 1, 2000. It also supplemented its application on May 9, 2001 (see Exhibit 2–2), clarifying the test standards it requests for recognition and the supplemental programs it wishes to use.

The applicant originally requested recognition for 18 test standards. However, the NRTL Program staff determined that 3 of these test standards are not ''appropriate test standards,'' within the meaning of 29 CFR 1910.7(c). The staff makes such determinations in processing NRTL applications. Therefore, OSHA would recognize TUVAM for the 15 test standards listed below (see List of Test Standards).

Some documents in the November 9 submission, and virtually all of its documents in the original application, have been designated as ''confidential'' by the applicant. We follow provisions of 29 CFR part 70 in determining whether we can or must disclose application information. This part generally deals with procedures to process a request for disclosure under the Freedom of Information Act (FOIA). Under subpart B of this part 70, information designated as confidential by a business submitter may be afforded protection under Exemption 4 of the FOIA. This exemption protects commercial or financial information, the disclosure of which would cause substantial competitive harm to the submitter.

As part of our normal process for handling applications, OSHA requested that the applicant provide reasons for designating application documents as confidential, and specifically whether disclosure would cause it substantial competitive harm. The applicant provided the necessary justification in its response dated November 9, 1999 (see Exhibit 2–1). Generally, the applicant maintains the 4 levels of operational documentation mentioned in international quality standards. It generally considers its level 3 and 4 documents to be confidential or privileged, and so stated in revising the designations in its November 9 response. These documents are detailed internal procedures that explain more specifically how the applicant does or will operate.

OSHA has evaluated the applicant's designations and determined that

disclosure of certain documents in the original application, and all or a portion of the documents in the November 9, April 28, and May 1 supplements to the application described above, could potentially give to prospective or current competitors knowledge that could cause the applicant substantial competitive harm. Therefore, under the provisions of 29 CFR part 70, those documents could be withheld from disclosure under Exemption 4 of the Freedom of Information Act (FOIA). Accordingly, we are not making them available for public review and have not included those documents in the public docket for the application, which we further describe later in this notice. OSHA has previously withheld from disclosure similar such documents in response to FOIA requests received concerning documents submitted by other NRTLs.

Staff of the NRTL Program performed an on-site review (assessment) of the Danvers, Massachusetts, facility on October 23–26, 2000. The staff performed the reviews of the sites at San Diego and New Brighton on December 4–8, 2000. In the on-site review report (see Exhibit 3), the program staff recommended a ''positive finding,'' signifying that the applicant appears to meet the requirements for recognition in 29 CFR 1910.7.

Regarding the merits of the application, the applicant has presented detailed documentation that describes how it currently performs its testing and certification activities. The policies, procedures, work instructions, methods, and other practices described in this documentation would be used in its operations as an NRTL. Where appropriate, it has supplemented or modified the policies and procedures to conform to OSHA's requirements for an NRTL under 29 CFR 1910.7.

TUVAM currently performs product testing and certification activities, primarily for purposes of showing conformity to European based testing standards, such as EN and IEC standards, as indicated in the review report. It provided forms it uses when performing tests required under EN 60950. One of the test standards for which it requests recognition is UL 1950, which is equivalent to EN60950 but includes the US deviations. TUVAM has also performed testing to US-based test standards, such as UL 1950. As part of its current certification activities, it conducts initial and follow-up inspections at manufacturers' facilities, one facet of the activities that NRTLs recognized by OSHA must perform. It also authorizes the use of certification marks, another aspect of the work that NRTLs must perform. For purposes of its certifications under OSHA's NRTL Program, TUVAM will utilize a US certification mark. At the time of preparation of this notice, the registration of this mark is still pending. As already mentioned, both TUVAM and TUVPSG would utilize the same registered certification mark for purposes of their NRTL certifications.

The four recognition requirements of 29 CFR 1910.7 are presented below, along with an explanation illustrating how TUVAM has met or plans to meet each of these requirements.

Capability

Section 1910.7(b)(1) states that for each specified item of equipment or material to be listed, labeled or accepted, the laboratory must have the capability (including proper testing equipment and facilities, trained staff, written testing procedures, and calibration and quality control programs) to perform appropriate testing.

The application and on-site review report indicate that TUVAM has adequate testing equipment and adequate facilities to perform the tests required under the test standards for which it seeks recognition. Security measures are in place to restrict or control access to their facility, and procedures exist for handling test samples. The application and report also indicate that testing and processing procedures are in place, and the application describes the program for the development of new testing procedures. The applicant submitted a listing and examples of specific test methods that it currently uses and would utilize for its proposed NRTL testing activities.

It utilizes outside calibration sources and does not intend to perform internal calibrations of equipment used for its NRTL testing activities. The application indicates that TUVAM maintains records on testing equipment, which include information on repair, routine maintenance, and calibrations. The application and on-site review report address personnel qualifications and training, and identify the applicant's staff involved with product testing, along with a summary of their education and experience. Also, the report indicates that TUVAM personnel have adequate technical knowledge for the work they perform. Moreover, the review report describes the applicant's quality assurance program, which is explained in more detail in its Integrated Management System (IMS) manual. Finally, the applicant performs internal system and internal technical audits of its operations on a regular basis.

Control Procedures

Section 1910.7(b)(2) requires that the NRTL provide certain controls and services, to the extent necessary, for the particular equipment or material to be listed, labeled, or accepted. They include control procedures for identifying the listed or labeled equipment or materials, inspections of production runs at factories to assure conformance with test standards, and field inspections to monitor and assure the proper use of identifying marks or labels.

The applicant has procedures and related documentation for initially qualifying a manufacturer and for performing the required follow-up inspections at a manufacturer's facility. In its procedures, TUVAM identifies criteria it will use to determine the frequency for performing these follow-up factory inspections. It has adopted the criteria detailed in OSHA policies for NRTLs, which specify that NRTLs perform no fewer than four (4) inspections per year at certain facilities and no fewer than two (2) inspections per year under certain conditions. The factory inspections would be one part of the activities that the applicant will utilize in controlling its certification mark. In its application, TUVAM included evidence of its application for registration of a TUV certification mark with the U.S. Patent and Trademark Office (USPTO). As previously mentioned, this mark is still pending approval by the USPTO.

The applicant has procedures for control and issuance of product certifications. According to the review report, TPS ''has been involved in a certification program for over ten years.'' As indicated in the report, the TPS Certification Body has been recently established under the TPS division but will operate in a manner consistent with the applicant's current certification practices, under which a Technical Certifier issues the formal product certification. As stated in the report, only those certifiers that are ''[TPS] employees and reside at one of the recognized sites will be authorized to certify'' a product for purposes of TUVAM's NRTL operations. The applicant maintains a detailed database of the product certifications, which would serve as its listing record. The application contains policies and terms and conditions to address control of a certification mark, and the procedures for such control are integral to more detailed procedures that the applicant uses for processing its certification

certificates. For purposes of OSHA's NRTL Program, control by the NRTL of its certification mark is uppermost in importance and procedures for such control must ensure that the NRTL's registered mark is applied to those products that the NRTL has certified. Such control must be proactive and not just reactive. TUVAM's control of a US registered certification mark under the type of certification process required in OSHA's NRTL Program regulations will be a new activity for the applicant, and we propose to include a condition related to this control.

Independence

Section 1910.7(b)(3) requires that the NRTL be completely independent of employers subject to the tested equipment requirements, and of any manufacturers or vendors of equipment or materials being tested for these purposes.

As previously stated, TUV Suddeutschland is currently the sole owner of TUVAM. In addition, the information reviewed by OSHA has not indicated that TUVAM has the kinds of relationships described in OSHA policy that would cause the applicant to fail to meet the independence requirement. This information shows that TUVAM does not own or control and is not owned or controlled by the kind of entities of concern to OSHA. In addition, OSHA's review of information on business activities and subsidiaries of TUVAM's parent company has not revealed any apparent conflicts of interest that could adversely influence the applicant's testing and certification activities. TUVAM has policies to protect against conflicts of interest by its employees.

Credible Reports/Complaint Handling

Section 1910.7(b)(4) provides that an NRTL must maintain effective procedures for producing credible findings and reports that are objective and without bias, as well as for handling complaints and disputes under a fair and reasonable system.

The applicant utilizes standardized formats for recording and reporting testing data and inspection data. It has procedures for evaluating and reporting the findings for testing and inspection activities to check conformance to all requirements of a test standard. The applicant provided examples of its test and inspection reporting forms.

Regarding the handling of complaints and disputes, the applicant's complaint and error management procedure provides the framework to handle complaints it receives from its clients or from the public or other interested parties. It maintains a detailed database that it uses as part of its quality assurance activities, which provides for recording and tracking complaint information. According to the review report, ''there have not been any complaints received concerning any of the certifications that have issued'' through the date of the review.

Test Standards

TUVAM seeks recognition for testing and certification of products for demonstration of conformance to the 15 test standards listed below, and OSHA has determined the standards are ''appropriate,'' within the meaning of 29 CFR 1910.7(c).

OSHA recognition of any NRTL for a particular test standard is limited to equipment or materials (i.e., products) for which OSHA standards require third party testing and certification before use in the workplace. Consequently, an NRTL's scope of recognition excludes any product(s) falling within the scope of the test standard for which OSHA has no testing and certification requirements.

List of Test Standards

UL 45 Portable Electric Tools
UL 50 Enclosures for Electrical Equipment
UL 67 Panelboards
UL 73 Motor-Operated Appliances
UL 508 Industrial Control Equipment
UL 751 Vending Machines
UL 813 Commercial Audio Equipment
UL 1004 Electric Motors
UL 1012 Power Units Other Than Class 2
UL 1244 Electrical and Electronic Measuring and Testing Equipment
UL 1950 Technology Equipment Including Electrical Business Equipment
UL 2601–1 Medical Electrical Equipment, Part 1: General Requirements for Safety
UL 3101–1 Electrical Equipment for Laboratory Use; Part 1: General Requirements
UL 3111–1 Electrical Measuring and Test Equipment, Part 1: General Requirements
UL 6500 Audio/Video and Musical Instrument Apparatus for Household, Commercial, and Similar General Use

The designations and titles of the above test standards were current at the time of the preparation of this notice.

Many of the Underwriters Laboratories (UL) test standards listed above are also approved as American National Standards by the American National Standards Institute (ANSI). However, for convenience in compiling the list, we use the designation of the standards developing organization (e.g., UL 1004) for the standard, as opposed to the ANSI designation (e.g., ANSI/UL 1004). Under our procedures, an NRTL recognized for an ANSI-approved test standard may use either the latest proprietary version of the test standard or the latest ANSI version of that standard, regardless of whether it is currently recognized for the proprietary or ANSI version. Contact ANSI or the ANSI web site (http://www.ansi.org) and click ''NSSN'' to find out whether or not a test standard is currently ANSI-approved.

Supplemental Programs

TUV America, Inc., also seeks to use the supplemental programs listed below, subject to the criteria detailed in the March 9, 1995 **Federal Register** notice (60 FR 12980, 3/9/95). That notice lists nine (9) programs and procedures (collectively, programs), eight of which (called supplemental programs) an NRTL may use to control and audit, but not actually to generate, the data relied upon for product certification. An NRTL's initial recognition always includes the first or basic program, which requires that all product testing and evaluation be performed in-house by the NRTL that will certify the product. The on-site review report indicates that TUVAM appears to meet the criteria for use of the following supplemental programs for which it has applied:

Program 2: Acceptance of testing data from independent organizations, other than NRTLs.
Program 3: Acceptance of product evaluations from independent organizations, other than NRTLs.
Program 4: Acceptance of witnessed testing data.
Program 5: Acceptance of testing data from non-independent organizations.
Program 6: Acceptance of evaluation data from non-independent organizations (requiring NRTL review prior to marketing).
Program 8: Acceptance of product evaluations from organizations that function as part of the International Electrotechnical Commission Certification Body (IEC–CB) Scheme.
Program 9: Acceptance of services other than testing or evaluation performed by subcontractors or agents.

OSHA developed these programs to limit how an NRTL may perform certain aspects of its work and to permit the activities covered under a program only when the NRTL meets certain criteria. In this sense, they are special conditions that the Agency places on an NRTL's recognition. OSHA does not consider

these programs in determining whether an NRTL meets the requirements for recognition under 29 CFR 1910.7. However, these programs help to define the scope of that recognition.

Conditions

As already indicated, TUVAM and TUVPSG plan to utilize the same U.S. registered certification mark for purposes of their NRTL certifications. This is a new undertaking for the applicant and although it has procedures for controlling a certification mark, it still needs to further develop and refine the detailed procedures it will use to control this particular mark. As a result, OSHA would conditionally recognize TUVAM subject to an assessment of the detailed procedures and practices for controlling this mark once they are in place.

The US registered mark is the only one that OSHA would recognize for TUVAM. In addition, only the sites listed in this notice will be able to authorize use of this mark for the TUVAM product certifications under the NRTL Program. Conversely, no other TUVAM laboratories or locations may authorize the use of this mark for product certifications under the NRTL Program. To ensure the applicant and the public understand this fact, OSHA plans to impose a condition to this effect. A similar condition was proposed in the March 16 notice for TUVPSG, mentioned above.

As also noted, the applicant has just adopted procedures concerning the criteria for the frequency at which it will conduct factory follow-up inspections. Here, too, it needs to refine these procedures to effectively and properly implement the criteria. OSHA would have to review TUVAM's approach in implementing the criteria for the twice-per-year inspections before it begins to conduct inspections at this frequency. As a result, OSHA would conditionally recognize TUVAM subject to an assessment of the details of this approach once it is in place.

Imposing the proposed conditions is consistent with OSHA's past recognition of certain organizations as NRTLs that met the basic requirements but needed to further develop or refine their procedures (for example, see 63 FR 68306 12/10/1998; and 65 FR 26637, 05/08/2000). Given the applicant's current breadth of activities in testing and certification, OSHA is confident that TUVAM would develop and implement procedures and practices to appropriately perform the activities in the areas noted above.

Therefore, OSHA would impose the following conditions in the final notice to officially recognize TUVAM as an NRTL. These conditions apply solely to TUVAM's operations as an NRTL and solely to those products that it certifies for purposes of enabling employers to meet OSHA product approval requirements. These conditions would be in addition to all other conditions that OSHA normally imposes in its recognition of an organization as an NRTL.

1. Within 30 days of certifying its first products under the NRTL Program, TUVAM will notify the OSHA NRTL Program Director so that OSHA may review TUVAM's implementation of its procedures for controlling its US registered certification mark in conjunction with use of this mark by TUV Product Services GmbH of Germany.

2. Only TUV America, Inc., or TUV Product Services GmbH may authorize the US registered certification mark currently owned by TUVAM, provided each one is recognized as an NRTL by OSHA. TUVAM may authorize the use of this mark, for purposes of its product certifications under the NRTL Program, only at the TUVAM sites recognized by OSHA.

3. Prior to conducting inspections of manufacturing facilities based on a frequency of twice per year, OSHA must review and accept the detailed procedures that TUVAM will utilize to determine when to use this frequency for such inspections.

Preliminary Finding

TUV America, Inc. (TUVAM) has addressed the requirements that must be met for recognition as an NRTL, as summarized above. In addition, the NRTL Program staff has performed on-site reviews (assessments) of TUVAM's facilities at Danvers, Massachusetts, San Diego, California, and New Brighton (Minneapolis), Minnesota and investigated the processes, procedures, practices, and general operations used by TUVAM. Discrepancies noted by the review staff were addressed by TUVAM following the on-site reviews, as detailed above, and are included as an integral part of the on-site review report (see Exhibit 3).

Following a review of the complete application file and the on-site review report, the NRTL Program staff has concluded that the applicant can be granted recognition as a Nationally Recognized Testing Laboratory for the 3 sites and the 15 test standards described above, subject to the conditions noted. The staff, therefore, recommended to the Assistant Secretary that the application be preliminarily approved.

Based upon the recommendation of the staff, the Agency has made a preliminary finding that TUV America, Inc., can meet the requirements, as prescribed by 29 CFR 1910.7, for recognition as a Nationally Recognized Testing Laboratory for the 3 sites and 15 test standards described above, subject to the conditions noted. This preliminary finding, however, does not constitute an interim or temporary approval of the application.

OSHA welcomes public comments, in sufficient detail, as to whether TUV America, Inc., has met the requirements of 29 CFR 1910.7 for its recognition as a Nationally Recognized Testing Laboratory. Your comment should consist of pertinent written documents and exhibits. To consider it, OSHA must receive the comment at the address provided above (see **ADDRESSES**) no later than the last date for comments (see **DATES** above). Should you need more time to comment, OSHA must receive your written request for extension at the address provided above (also see **ADDRESSES**) no later than the last date for comments (also see **DATES** above). You must include your reason(s) for any request for extension. OSHA will limit an extension to 30 days unless the requester justifies a longer period. We may deny a request for extension if it is frivolous or otherwise unwarranted. You may obtain or review copies of TUVAM's application, the additional submissions, the on-site review report, and all submitted comments, as received, by contacting the Docket Office, Room N2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. You should refer to Docket No. NRTL2–2001, the permanent record of public information on TUVAM's recognition application.

The NRTL Program staff will review all timely comments and, after resolution of issues raised by these comments, will recommend whether to grant TUVAM's application for recognition. The Agency will make the final decision on granting the recognition and, in making this decision, may undertake other proceedings that are prescribed in Appendix A to 29 CFR 1910.7. OSHA will publish a public notice of this final decision in the **Federal Register**.

Signed at Washington, D.C. this 15th day of November, 2001.

John L. Henshaw,

Assistant Secretary.

[FR Doc. 01–29233 Filed 11–21–01; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2001–7 CARP SD 2000]

Ascertainment of Controversy for the 2000 and 2001 Satellite Royalty Funds

AGENCY: Copyright Office, Library of Congress.

ACTION: Suspension of filing deadline and request for comments.

SUMMARY: The Copyright Office of the Library of Congress is suspending the current filing deadline for comments and Notices of Intent to Participate for distribution of the 2000 and 2001 satellite royalty funds and seeks comment on a request for a new filing deadline of January 15, 2002.

DATES: Comments are due no later than December 10, 2001.

ADDRESSES: If sent by mail, an original and five copies of written comments should be addressed to: Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, DC 20024. If hand delivered, an original and five copies should be brought to: Office of the General Counsel, James Madison Memorial Building, Room 403, First and Independence Avenue, S.E., Washington, DC 20540.

FOR FURTHER INFORMATION CONTACT: David O. Carson, General Counsel, or William J. Roberts, Jr., Senior Attorney for Compulsory Licenses, Copyright Arbitration Royalty Panels, P.O. Box 70977, Southwest Station, Washington, DC 20024. Telephone (202) 707–8380. Telefax: (202) 252–3423.

SUPPLEMENTARY INFORMATION: Each year satellite carriers submit royalties to the Copyright Office for the retransmission of over-the-air broadcast signals to their subscribers. 17 U.S.C. 119. These royalties are, in turn, distributed in one of two ways to copyright owners whose works were included in a retransmission of an over-the-air broadcast signal and who timely filed a claim for royalties with the Copyright Office. The copyright owners may either negotiate the terms of a settlement as to the division of the royalty fees, or the Librarian of Congress may convene a Copyright Arbitration Royalty Panel (''CARP'') to determine the distribution of the royalty fees that remain in controversy. *See* 17 U.S.C. chapter 8.

On October 30, 2001, the Library of Congress published a Notice in the **Federal Register** requesting comments from interested parties as to the existence of controversies over the distribution of 2000 satellite royalty fees collected under 17 U.S.C. 119.66 FR 54789 (October 30, 2001). The Library requested that interested parties submit their comments, along with Notices of Intent to Participate in the 2000 distribution proceeding, by November 29, 2001. In addition, the Library sought comment on a petition for royalty distribution filed by the Public Broadcasting Service (''PBS''), seeking collection of 2000 and 2001 royalties submitted under 17 U.S.C. 119(b) for the PBS satellite feed.

On November 6, 2001, the Motion Picture Association of America, Inc. (''MPAA'') filed a motion seeking an extension of the November 29, 2001, deadline to January 15, 2002. MPAA's motion can be found at *http://www.loc.gov/copyright/carp/mpaamotion.pdf*. MPAA asserts that it cannot submit its Notice of Intent to Participate until the Copyright Office completes its examination of claims filed for the 2000 satellite funds. Once this examination is completed, MPAA will need time to secure representation agreements from its claimants before submitting its Notice of Intent to Participate. The extension of the filing period until January 15, 2002 will, in the opinion of MPAA, allow it sufficient time to prepare its Notice.

In order to consider MPAA's motion, it is necessary to suspend the current filing deadline of November 29, 2001. Consequently, interested parties need not file at this time their comments on the existence of controversies to the distribution of the 2000 satellite royalty funds, their comments on the PBS motion for distribution, or their Notices of Intent to Participate until further notice.

In the meantime, the Library seeks comment as to MPAA's motion and the advisability of extending the filing deadline until January 15, 2002, for comments on the existence of controversies and Notices of Intent to Participate.

Dated: November 19, 2001.

David O. Carson,

General Counsel.

[FR Doc. 01–29278 Filed 11–21–01; 8:45 am]

BILLING CODE 1410–33–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–148)]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that Digital Interface Systems, Inc., 241 Federal Plaza West, Suite 204, Youngstown, Ohio 44503, has applied for an exclusive license to practice the invention described and claimed in U.S. Patent No. 5,905,568, entitled ''Stereo Imaging Velocimetry,'' which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Glenn Research Center.

DATES: Responses to this notice must be received by December 10, 2001.

FOR FURTHER INFORMATION CONTACT: Kent N. Stone, Patent Attorney, NASA Glenn Research Center, 21000 Brookpark Road, Cleveland, OH 44135, telephone (216) 433–8855.

Dated: November 14, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–29212 Filed 11–21–01; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–149)]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that Femto Trace, Inc. of La Cresenta, California, has applied for an exclusive license to practice the inventions described and claimed in U.S. Patent No. 4,649,278, entitled ''Generation of Intense Negative Ion Beams,'' U.S. Patent No. 4,933,551, entitled ''Reversal Electron Attachment Ionizer for Detection of Trace Species,'' U.S. Patent No. 5,374,828, entitled ''Method for Trace Oxygen Detection,'' and U.S. Patent No. 5,670,378, entitled ''Electron Reversal Ionizer for Detection of Trace Species Using a Spherical Cathode,'' all of which are assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to the NASA Management Office—JPL.

Responses to this notice must be received by December 10, 2001.

FOR FURTHER INFORMATION CONTACT: John Kusmiss, Patent Counsel, NASA

Management Office—JPL, 4800 Oak Grove Drive, Mail Stop 180–802, Pasadena, CA 91109–8099.

Dated: November 14, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–29213 Filed 11–21–01; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Advisory Panel

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that five meetings of the Combined Arts Advisory Panel to the National Council on the Arts (Access and Heritage/Preservation categories) will be held at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 as follows:

Opera: November 26, 2001, Room 716. A portion of this meeting, from 4 p.m. to 4:45 p.m., will be open to the public for policy discussion. The remaining portions of this meeting, from 10 a.m. to 4 p.m. and 4:45 p.m. to 5:30 p.m. will be closed.

Music (Heritage/Preservation category): November 27, 2001, Room 714. A portion of this meeting, from 4:30 p.m. to 5:30 p.m., will be open to the public for policy discussion. The remaining portions of this meeting, from 9 a.m. to 4:30 p.m. and from 5:30 p.m. to 6 p.m., will be closed.

Music (Access category): November 28–30, 2001, Room 714. A portion of this meeting, from 1 p.m. to 2:30 p.m. on November 30th, will be open to the public for policy discussion. The remaining portions of this meeting, from 9 a.m. to 5:30 p.m. on November 28th and 29th, and from 9 a.m. to 1 p.m. and 2:30 p.m. to 3:30 p.m. on November 30th, will be closed.

Literature: December 3–4, 2001, Room 730. A portion of this meeting, from 11 a.m. to 12 p.m. on December 4th, will be open to the public for policy discussion. The remaining portions of this meeting, from 9 a.m. to 6 p.m. on December 3rd, and from 9 a.m. to 11 a.m. and 12 p.m. to 3 p.m. on December 4th, will be closed.

Museums: December 11–13, 2001, Room 716. A portion of this meeting, from 9 a.m. to 10 p.m. on December 13th, will be open to the public for policy discussion. The remaining portions of this meeting, from 9 a.m. to 6:30 p.m. on December 11th and 12th, and from 10 a.m. to 12:30 p.m. on December 13th, will be closed.

The closed portions of these meetings are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 22, 2001, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels that are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC, 20506, or call 202/682–5691.

Dated: November 16, 2001.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 01–29199 Filed 11–21–01; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC. 20506.

FOR FURTHER INFORMATION CONTACT: Laura S. Nelson, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC. 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1933, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* December 4, 2001.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Library & Archival Preservation and Access/Reference Materials, submitted to the Division of Preservation and Access at the July 1, 2001 deadline.

2. *Date:* December 6, 2001.
Time: 8:30 a.m. to 5:00 p.m.
Room: M–07.
Program: This meeting will review applications for Collaborative Research in Archaeology, submitted to the Division of Research Programs at the September 1, 2001 deadline.

3. *Date:* December 7, 2001.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review applications for Library & Archival Preservation and Access/Reference Materials, submitted to the Division of Preservation and Access at the July 1, 2001 deadline.

4. *Date:* December 7, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Exemplary Education Projects, submitted to the Division of Education at the October 15, 2001 deadline.

5. *Date:* December 7, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: 527.
Program: This meeting will review applications for Collaborative Research in American History and Studies, submitted to the Division of Research Programs at the September 1, 2001 deadline.

6. *Date:* December 10, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Exemplary Education Projects, submitted to the Division of Education at the October 15, 2001 deadline.

7. *Date:* December 10, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: M–07.
Program: This meeting will review applications for Collaborative Research in Editions I, submitted to the Division of Research Programs at the September 1, 2001 deadline.

8. *Date:* December 11, 2001.
Time: 8:45 a.m. to 5:00 p.m.
Room: 527.
Program: This meeting will review applications for Collaborative Research in Non-Western Studies, submitted to the Division of Research Programs at the September 1, 2001 deadline.

9. *Date:* December 14, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Exemplary Education Projects, submitted to the Division of Education at the October 15, 2001 deadline.
10. *Date:* December 14, 2001.
Time: 8:30 a.m. to 5:00 p.m.
Room: 527.
Program: This meeting will review applications for Collaborative Research in Arts and Literature, submitted to the Division of Research Programs at the September 1, 2001 deadline.
11. *Date:* December 17, 2001.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications for Exemplary Education Projects, submitted to the Division of Education at the October 15, 2001 deadline.

Laura S. Nelson,

Advisory Committee Management Officer.

[FR Doc. 01–29171 Filed 11–21–01; 8:45 am]

BILLING CODE 7536–01–M

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Review of an Existing Information Collection: OPM 2809

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget a request for review of an existing information collection. OPM 2809, Health Benefits Registration Form, is used by annuitants and former spouses to elect, cancel, or change health benefits enrollment during periods other than open season.

There are approximately 30,000 changes to health benefits coverage per year. Of these, 20,000 are submitted on form OPM 2809 and 10,000 verbally or in written correspondence. Each form takes approximately 45 minutes to complete; data collection by telephone or mail takes approximately 10 minutes. The annual burden for the form is 15,000 hours; the burden not using the form is 1,667 hours. The total burden is 16,667.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, FAX (202) 418–3251 or E-mail to *mbtoomey@opm.gov.* Please provide a mailing address with your request.

DATES: Comments on this proposal should be received on or before January 22, 2002.

ADDRESSES: Send or deliver comments to Ronald W. Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349A, Washington, DC 20415–3540.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Donna G. Lease, Budget & Administrative Services Division, (202) 606–0623.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 01–29228 Filed 11–21–01; 8:45 am]

BILLING CODE 6325–50–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Review of a Revised Information Collection: RI 20–80

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for review of a revised information collection. RI 20–80, Alternative Annuity Election, is used for individuals who are eligible to elect whether to receive a reduced annuity and a lump-sum payment equal to their retirement contributions (alternative form of annuity) or an unreduced annuity and no lump sum.

Approximately 200 RI 20–80 forms are completed annually. We estimate it takes approximately 20 minutes to complete the form. The annual burden is 67 hours.

Comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, FAX (202) 418–3251 or email to *mbtoomey@opm.gov.* Please include a mailing address with your request.

DATES: Comments on this proposal should be received on or before January 22, 2002.

ADDRESSES: Send or deliver comments to, Ronald W. Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349A, Washington, DC 20415–3540.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Donna G. Lease, Team Leader, Forms Analysis and Design, Budget and Administrative Services Division, (202) 606–0623.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 01–29230 Filed 11–21–01; 8:45 am]

BILLING CODE 6325–50–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review; Comment Request for Review of a Revised Information Collection: RI 38–47

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) has submitted to the Office of Management and Budget a request for review of a revised information collection. Information and Instructions on Your Reconsideration Rights, RI 38–47, outlines the procedures required to request reconsideration of an initial OPM decision about Civil Service or Federal Employees retirement, retired Federal or Federal Employee Health Benefits requests to enroll or change enrollment, or Federal Employees' Group Life Insurance coverage. The form lists the procedures and time periods required for requesting reconsideration.

Approximately 3,100 annuitants and survivors request reconsideration annually. We estimate it takes approximately 45 minutes to apply. The annual burden is 2,325 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–

8358, FAX (202) 418–3251 or E-mail to *mbtoomey@opm.gov*. Please include your mailing address with your request.

DATES: Comments on this proposal should be received on or before December 24, 2001.

ADDRESSES: Send or deliver comments to—

Ron Melton, Chief, Operations Support Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3349A, Washington, DC 20415–3540

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW, Room 10235, Washington, DC 20503

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Donna G. Lease, Budget & Administrative Services Division, (202) 606–0623.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 01–29227 Filed 11–21–01; 8:45 am]

BILLING CODE 6325–50–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review: Comment Request; Review of Revised Information Collection: OPM 1647

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management submitted a request for renewal of authorization for a revised information collection to the Office of Management and Budget. OPM Form 1647, Combined Federal Campaign Eligibility Application, is used to review the eligibility of national, international, and local charitable organizations that wish to participate in the Combined Federal Campaign.

We estimate 1,400 Form 1647's will be completed annually. Each form takes approximately three hours to complete. The annual estimated burden is 4,200 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, FAX (202) 418–3251 or E-mail to *mbtoomey@opm.gov*. Please include a mailing address with your request.

DATES: Comments on this proposal should be received on or before December 24, 2001.

ADDRESSES: Send or deliver comments to: Curtis Rumbaugh, Office of CFC Operations, U.S. Office of Personnel Management, 1900 E Street, NW, Room 5450, Washington, DC 20415; and

Joseph Lackey, OPM Desk Officer, Office of Information & Regulatory Affairs, Office of Management & Budget, New Executive Office Building, NW, Room 10235, Washington, DC 20503.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 01–29229 Filed 11–21–01; 8:45 am]

BILLING CODE 6325–46–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Myers Industries, Inc., Common Stock, no par Value) From the American Stock Exchange LLC File No. 1–8524

November 15, 2001.

Myers Industries, Inc., an Ohio corporation (''Issuer''), has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to section 12(d) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 12d2–2(d) hereunder,[2] to withdraw its Common Stock, no par value (''Security''), from listing and registration on the American Stock Exchange LLC (''Amex'' or ''Exchange'').

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in effect in the State of Ohio, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration. The Amex has in turn informed the Issuer that it does not object to the proposed withdrawal of the Issuer's Security from listing and registration on the Exchange.

The Board of Trustees (''Board'') of the Issuer approved a resolution on September 19, 2000 to withdraw the Issuer's Security from listing on the Amex and to list such Security on the New York Stock Exchange, Inc. (''NYSE''), effective May 1, 2001. In making the decision to withdraw its Security from the Amex, the Board considered the potential to increase institutional interest and the benefit to its capital structure by listing on the NYSE. The Issuer stated that trading in the Security on the Amex ceased on April 30, 2001, and trading in the Security began on the NYSE at the opening of business on May 1, 2001.

The Issuer's application relates solely to the withdrawal of the Security from listing and registration on the Amex and shall have no effect upon the Security's continued listing and registration on the NYSE under section 12(b) of the Act.[3]

Any interested person may, on or before December 10, 2001, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–29198 Filed 11–21–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27467]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

November 16, 2001.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the

[1] 15 U.S.C. 78l(d).

[2] 17 CFR 204.12d2–2(d).

[3] 15 U.S.C. 78l(b).

[4] 17 CFR 200.30–3(a)(1).

application(s) and/or declaration(s) should submit their views in writing by December 10, 2001, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After December 10, 2001, the application(s) and/or declaration(s), as filed or as amended, may be granted and /or permitted to become effective.

National Fuel Gas Company (70–9987)

National Fuel Gas Company (''National''), a registered holding company, 10 Lafayette Square, Buffalo, New York 14203, has filed an application-declaration under sections 32 and 33 of the Act and rule 53 under the Act.

National seeks an increase in its aggregate investment limit in exempt wholesale generators, as defined in section 32 of the Act, (''EWGs''), and foreign utility companies, as defined in section 33 of the Act, (''FUCOs''). By order of the Commission dated March 20, 1998 (HCAR No. 26847) as modified by order dated April 21, 2000 (HCAR No. 27170) (''1998 Order''), National and its subsidiaries are authorized to engage in a program of external financing, intrasystem financing and other related transactions for the period through December 31, 2002. Among other approvals granted, the Commission authorized National to: (i) Issue and sell additional long-term debt and equity securities not to exceed $2 billion outstanding at any one time; (ii) issue and sell up to $750 million principal amount of short-term debt in the form of commercial paper and borrowings under credit facilities; and (iii) guarantee securities of its subsidiaries and provide other forms of credit support with respect to obligations of its subsidiaries as may be necessary or appropriate to enable such subsidiaries to carry on in the ordinary course of business in an aggregate amount not to exceed $2 billion outstanding at any one time.

National was also authorized in the 1998 Order to use the proceeds of authorized financing to invest in and enter into guarantees with respect to the obligations of EWGs and FUCOs, provided that its ''aggregate investment'' (as defined under rule 53 of the Act) in EWGs and FUCOs does not exceed 50% of its consolidated retained earnings (as defined in rule 53), except for short-term borrowings by National to provide funds to the National System Money Pool, which may not be used to fiance the acquisition of any interest in a FUCO or EWG. As of August 31, 2001, National's aggregate investment in EWEGs and FUCOs was approximately $130,074,000, or 22.3% of National's average consolidated retained earnings ($583,737,000) for the four quarters ended June 30, 2001.

National is now requesting, under rule 53(c), authority to utilize the proceeds of financing and guarantees, as authorized under the 1998 Order or in any subsequent proceeding, to increase its ''aggregate investment'' in EWGs and FUCOs (''Exempt Projects'') to $750 million, which is equal to approximately 128% of National's average consolidated retained earnings for the four quarters ended June 30, 2001.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29249 Filed 11–21–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45061; File No. SR–Amex–2001–58]

Self Regulatory Organizations; American Stock Exchange LLC; Order Granting Approval to Proposed Rule Change Relating to the Billing of the Annual Fee for Listed Companies

November 15, 2001.

On August 2, 2001, the American Stock Exchange LLC filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] a proposed rule change that will, in the calendar year in which a company first lists, prorate the annual fee to reflect the portion of the year that the company has been listed, and make the annual fee payable in December based on the total number of outstanding shares at the time of original listing.

The proposed rule change was published for comment in the **Federal Register** on August 22, 2001,[3] The Commission received no comments on the proposal.

The Commission finds that the proposed rule exchange is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[4] and, in particular, the requirements of section 6 of the Act[5] and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with section 6(b)(5) of the Act[6] because it is designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

It is therefore ordered, pursuant to section 19(b)(2) of the Act[7] that the proposed rule change (File No. SR–Amex–2001–58) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29251 Filed 11–21–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45068; File No. SR–Amex–2001–98]

Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change by the American Stock Exchange LLC to Reinstate and Increase Options Transaction Charges

November 16, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934[1] notice is hereby given that on November 8, 2001, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1)

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 44712 (August 22, 2001), 66 FR 44189.

[4] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

change as described in Items, I, II, and III below, which Items have been prepared by self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to reinstate and increase options transaction charges in select products. The Exchange proposes to increase the fees charged to (1) customers for transactions in index options from $0.10 to $0.15; and (2) member firms and non-member broker dealers for transactions in index options from $0.11 to $0.15. In addition, the Exchange is proposing to reinstate a customer transaction charge for equity options on the S&P 100 iShares. The transaction charge will be $0.15 per contract side.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

(1) Purpose

Transaction charges are imposed on options trades executed on the Exchange. The charges vary depending on whether the transaction involves an equity or index option and whether the transaction is executed for a specialist's account, a registered options trader account, a member firm's proprietary account, a non-member broker-dealer, or a customer account. The Amex also imposes a charge for clearance of options trades and an options floor brokerage charge, which also depends upon the product and the type of account for which the trade is executed. In April 2000, the Exchange eliminated transaction, floor brokerage, and clearance charges for customer equity option trades. At that time, fees charged to customers for transactions in index options remained unchanged at $0.10 per contract.

The Exchange is now proposing to increase the fees charged to (1) customers for transactions in index options from $0.10 to $0.15; and (2) member firms and non-member broker dealers for transactions in index options from $0.11 to $0.15. In addition, the Exchange is proposing to reinstate a customer transaction charge for equity options on the S&P 100 iShares. The transaction charge will be $0.15 per contract side. The Exchange believes that these increases are necessary due to the increasing costs incurred in developing and implementing new technology for the fast and efficient trading of options.

(2) Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act [2] in general and furthers the objectives of section 6(b)(4) of the Act [3] in particular in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld form the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–2001–98 and should be submitted by December 14, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29253 Filed 11–21–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45067; File No. SR–CBOE–2001–56]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval to Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Firm Disseminated Market Quotes

November 16, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 22, 2001, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to

[2] 15 U.S.C. 78f(b).

[3] 15 U.S.C. 78f(b)(4).

[4] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

grant accelerated approval to the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend CBOE Rule 8.51, Firm Disseminated Market Quotes, to address customer limit orders. Below is the text of the proposed rule change. Additions are italicized.

Rule 9.51 Firm Disseminated Market Quotes

(a)–(b) no change
(c) Firm Quote Size
(1) no change
(2) The firm quote requirement size for non-broker-dealer orders shall be the size that the Exchange periodically publishes along with the quotes disseminated to vendors. In the event the Exchange has not published a size along with its quotes for a particular series, then the firm quote requirement size for non-broker-dealer orders shall be that size published by the Exchange in a different manner (e.g., on its website). The Exchange also will publish separately the firm quote requirement size for broker-dealer orders. In the case of broker-dealer orders, if the size for a particular series disseminated along with the quotes is less than the size published for broker-dealer orders, then the firm quote requirement for broker-dealer orders shall be the size published along with the quotes.

(a) *When the disseminated quote represents a customer limit order in EBook, the firm quote requirement for non-broker-dealer orders shall be the greater of the size of the customer limit order or a size predetermined by the appropriate FPC. When the disseminated quote represents both a customer limit order in EBook and the trading crowd's quote, the firm quote requirement for non-broker-dealer orders shall be the aggregate size of the customer limit order and the size that the Exchange periodically publishes for that particular series.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On November 17, 2001, the Commission amended rule 11Ac1–1 under the Act (''Quote Rule'')[3] to require options exchanges to publish firm quotes. The amended Quote Rule requires options exchanges to either: (1) comply with the Quote Rule as it applies in the equity markets and collect from their members and make available to vendors the size associated with each quotation; or (2) establish by rule and periodically publish the quotation size for which their members' quotations are firm. On March 30, 2001, the Exchange submitted a proposal to amend CBOE rule 8.51, *Firm Disseminated Market quotes*, to conform to the requirements of the Quote Rule. The Commission approved this proposal initially on a pilot basis on April 2, 2001[4] and, subsequently, on a permanent basis on June 2, 2001.[5] This filing amends CBOE rule 8.51 to codify the Exchange's firm quote treatment of customer limit orders.

CBOE does not currently have the systems capability to decrement actual quotation size to reflect executions except when the quotation size represents an order in EBook. For this reason, when Autoquote or a manual quote establishes the best price on the Exchange, the Exchange's firm quote requirement for non-broker-dealer orders is the size that the Exchange periodically publishes on its website and along with the bid-ask quotes disseminated to vendors.[6]

When a customer limit order in EBook establishes the best bid or offer, however, CBOE complies with the Quote Rule in a different manner.[7] As discussed above, CBOE systems are able to decrement disseminated size for executions when the disseminated size represents a booked order. For this reason, when a customer limit order in EBook establishes the best bid or offer, CBOE disseminates the actual size of the booked limit order. In this instance, the Exchange must be firm for the greater of its disseminated size or a number predetermined by the appropriate floor procedure committee (''FPC''). The effect of this provision is two-fold. First, it ensures that the Exchange will be firm for at least the size of the disseminated booked order. Second, it also allows the appropriate FPC to establish a higher firm quote size guarantee when a booked order is the prevailing price. For example, in conjunction with Automated Book Price Split-price, if the equity floor procedure committee establishes a book price commitment quantity of ten contracts, it could correspondingly establish the minimum firm quote size guarantee at ten contracts. Thus, the Exchange would be firm for either the size of the booked order or ten contracts, whichever is greater. In no event would the firm quote size be smaller than the actual size of the disseminated booked order. The size of the minimum firm quote guarantee would be published on the CBOE Web site.

When a customer limit order in EBook matches the best bid or offer of the trading crowd, the size disseminated to OPRA, as well as the firm quote requirement, is the aggregate of the booked order and the size that the Exchange periodically publishes. For example, if in a particular series EBook contains an order for eleven contracts and the firm quote size as published on the Exchange's Web site is 50 contracts, then the disseminated size as well as the firm quote size would be 61 contracts for that series. When trades execute against the booked order, however, the disseminated size would decrement. When executions extinguish the booked order, the firm quote requirement would be the size that the Exchange periodically publishes on its Web site and along with the bid-ask quotes disseminated to vendors.[8] To codify the firm quote rules pertaining to customer limit orders, the Exchange proposes to add section (c)(2)(a) to CBOE Rule 8.51.

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[3] 17 CFR 240.11Ac1–1. *See* Exchange Act Release No. 43591 (Nov. 17, 2000), 65 FR 75439 (Dec. 1, 2000).

[4] *See* Exchange Act Release No. 44145 (April 2, 2001), 66 FR 18662 (April 10, 2001) (approving SR–CBOE–2001–15 on a pilot basis.

[5] *See* Exchange Act Release No. 44383 (June 2, 2001), 66 FR 30959 (June 8, 2001) (approving SR–CBOE–2001–15 on a permanent basis.

[6] *See* CBOE rule 8.51(c)(2).

[7] Book Market Indicators are disseminated to Options Price Reporting Authority (''OPRA'') when the book bid, offer, or both improve, or equal the Designated Primary Market Marker/Crowd (''DPM/Crowd'') quote. If the Book Bid improves or equals the DPM/Crowd market bid, then the Book Market Indicator ''B'' will be disseminated with the quote to OPRA. If the Book Offer improves or matches the DPM/Crowd market offer, then the Book Market Indicator ''O'' is disseminated with the quote. If the Book Bid and Offer improves or equals the DPM/Crowd market, then the Book Market Indicator ''C'' is disseminated with the quote.

[8] Using the above example, an execution of 12 contracts (which would extinguish the booked order of 11 contracts) would result in a new firm quote requirement, which would be the size (*i.e.,* 50 contracts) that appears on the CBOE Web site.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with and furthers the objectives of section 6 of the Act in general, and in particular, with section 6(b)(5),[9] in that it is designed to perfect the mechanisms of a free and open market and a national market system, protect investors and the public interest, and promote just and equitable principles of trade by increasing transparency and by providing the market place with more information upon which to base order routing decisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to section 19(b)(2) of the Act,[10] the Exchange requests accelerated effectiveness of this rule filing. The Exchange believes that acceleration will enable it to continue uninterrupted its compliance with the Quote Rule. Moreover, the CBOE believes that acceleration will enable it to provide greater liquidity guarantees to customers when customer limit orders match the best bid or offer of the trading crowd. For these reasons, the Exchange believes it is both appropriate and in the public interest of investors for the Commission to accelerate the effective date of this filing.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All submissions should refer to File No. SR–CBOE–2001–56 and should be submitted by December 14, 2001.

V. Commission Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful consideration, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange,[11] and, in particular, section 6(b)(5) of the Act [12] in that the proposed rule change has been designed to remove impediments to and to perfect the mechamism of a free and open market and a national market system, while also protecting investors and the public interest. Specifically, the Commission believes that by disseminating the size of customer limit orders and providing a firm quote at a guaranteed size equal to the aggregate of a customer limit order and the crowd guarantee at the same price, the proposed rule change should provide increased transparency to the benefit of market participants that trade listed options.

The Commission finds good cause, consistent with section 19(b)(2) of the Act,[13] for granting the Exchange's request for approval of the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission believes that granting accelerated approval to the proposed rule change should allow the CBOE to continue its compliance with the Quote Rule without interruption or delay.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[14] that the Exchange's proposed rule change (File No. SR–CBOE–2001–56) is approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Margaret H. McFarland,

Deputy Secretary.

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[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(2).

[11] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(2).

[14] 15 U.S.C. 78s(b)(2).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45062; File No. SR–CHX–2001–21]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 by the Chicago Stock Exchange, Incorporated To Extend a Pilot Rule Interpretation Relating to Trading of Nasdaq/NM Securities in Subpenny Increments

November 15, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 30, 2001, the Chicago Stock Exchange, Incorporated (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On November 6, 2001, the Exchange filed an amendment that completely replaces and supersedes the original proposal.[3] The Exchange filed the proposal pursuant to section 19(b)(3)(A) of the Act,[4] and Rule 19b–4(f)(6) [5] thereunder, which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend through January 14, 2002, the pilot rule interpretation relating to the trading of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* October 31, 2001 letter from Kathleen M. Boege, Associate General Counsel, CHX, to Alton S. Harvey, Division of Market Regulation (''Division''), Commission and attachments (''Amendment No. 1'') *See* November 13, 2001 telephone conversation between Kathleen M. Boege, CHX, and Joseph Morra, Special Counsel, Division, Commission.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6). The Commission waived the 5-day pre-filing notice requirement.

Nasdaq/NM securities in subpenny increments. The pilot is due to expire on November 5, 2001. The CHX does not propose to make any substantive or typographical changes to the pilot; the only change is an extension of the pilot's expiration date through January 14, 2002. The text of the proposal is available at the Commission and at the CHX.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for its proposal and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On April 6, 2001, the Commission approved, on a pilot basis through July 9, 2001, a pilot rule interpretation (CHX Article XXX, Rule 2, Interpretation and Policy .06 ''Trading in Nasdaq/NM Securities in Subpenny Increments'') [6] that requires a CHX specialist (including a market maker who holds customer limit orders) to better the price of a customer limit order in his book which is priced at the national best bid or offer (''NBBO'') by at least one penny if the specialist determines to trade with an incoming market or marketable limit order. The pilot was later extended through November 5, 2001.[7] The CHX now proposes to extend the pilot through January 14, 2002. The CHX proposes no other changes to the pilot, other than extending it through January 14, 2002.

2. Statutory Basis

The CHX believes the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange and, in particular, with the requirements of section 6(b).[8] In particular, the CHX believes the proposal is consistent with section 6(b)(5) of the Act [9] in that it is designed to promote just and equitable principles of trade, to remove impediments to, and to perfect the mechanism of, a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act [10] and rule 19b–4(f)(6) thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange has requested that the Commission accelerate the operative date. The Commission finds good cause to designate the proposal both effective and operative upon filing with the Commission because such designation is consistent with the protection of investors and the public interest. Acceleration of the operative date will allow the pilot to continue uninterrupted through January 14, 2002, the deadline for which self-regulatory organizations must file proposed rule changes to set the minimum price variation for quoting in a decimals environment. For these reasons, the Commission finds good cause to designate that the proposal is both effective and operative upon filing with the Commission.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to file number SR–CHX–2001–21 and should be submitted by December 14, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29250 Filed 11–21–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45066; File No. SR–CHX–2001–23]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Stock Exchange, Incorporated to Extend a Pilot Relating to Participation in Crossing Transactions Effected on the Exchange Floor

November 15, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2001, the Chicago Stock Exchange,

[6] *See* Securities Exchange Act Release No. 44164 (April 6, 2001), 66 FR 19263 (April 13, 2001) (SR–CHX–2002–07).

[7] *See* Securities Exchange Act Release No. 44535 (July 10, 2001), 66 FR 37251 (July 17, 2001 (SR–CHX–2001–15).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78S(B)(3)(a).

[11] 17 CFR 240.19b–4(f)(6).

[12] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Incorporated (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed pursuant to section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6)[4] thereunder, which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend through January 14, 2002, a pilot relating to participation in crossing transactions effected on the Exchange. The CHX does not propose to make any substantive or typographical changes to the pilot; the only change is an extension of the pilot's operation through January 14, 2002. The text of the proposed rule change is available at the Commission and at the CHX.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for its proposal and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 24, 2000, the Commission approved, on a pilot basis through February 28, 2001, a pilot rule change to CHX Article XX, Rule 23[5] that permits a CHX floor broker to consummate crossing transactions involving 5,000 shares or more, without interference by any specialist or market maker, if, prior to presenting the cross transaction, the floor broker first requests a quote for the subject security. On February 23, 2001, the pilot was extended through July 9, 2001[6] and rendered applicable to both Dual Trading System issues and Nasdaq/NM securities. The CHX inadvertently did not seek continued extension of the pilot before the July 9, 2001 expiration date. The Exchange now proposes to extend the pilot through January 14, 2002. The Exchange notes that despite the lapse of the pilot rule, CHX members have continued to adhere to the provisions of the pilot rule, which rule largely codified long-standing custom and practice on the CHX floor.

2. Statutory Basis

The CHX believes the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of section 6(b).[7] In particular, the CHX believes the proposal is consistent with section 6(b)(5) of the Act[8] in that it is designed to promote just and equitable principles of trade, to remove impediments to, and to perfect the mechanism of, a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange has requested that the Commission accelerate the operative date. The Commission finds good cause to designate the proposal both effective and operative upon filing with the Commission because such designation is consistent with the protection of investors and the public interest. Acceleration of the operative date will allow the pilot to operate through January 14, 2002, the deadline for which self-regulatory organizations must file proposed rule changes to set the minimum price variation for quoting in a decimals environment. For these reasons, the Commission finds good cause to designate that the proposal is both effective and operative upon filing with the Commission.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to file number SR–CHX–2001–23 and should be submitted by December 14, 2001.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6). The CHX provided the Commission written notice of its intent to file the proposal on October 31, 2001. The Exchange has asked the Commission to waive the 30-day operative delay to allow the proposal to be effective upon filing with the Commission.

[5] See Securities Exchange Act Release No. 43203 (August 24, 2000), 65 FR 53067 (August 31, 2001) (SR–CHX–00–13).

[6] See Securities Exchange Act Release No. 44000 (February 23, 2001), 66 FR 13361 (March 5, 2001) (SR–CHX–00–27).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29252 Filed 11–21–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Self-Regulatory Organizations; Government Securities Clearing Corporation; Order Approving a Proposed Rule Change Relating to an Earlier Daily Trade Data Submission Deadline and the Imposition of Fines for Late Submissions

November 14, 2001.

[Release No. 34–45053; File No. SR–GSCC–00–09]

On August 23, 2000, the Government Securities Clearing Corporation (''GSCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–GSCC–00–09) pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposal was published in the **Federal Register** on August 22, 2001.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The proposed rule change will change GSCC's daily trade submission deadline from 10:00 p.m. to 8:00 p.m. Eastern Standard Time (''EST'') and impose a fine schedule for late trade submissions.

GSCC first announced its intention to move to an earlier trade submission deadline in 1997 in a White Paper detailing GSCC's plans for providing straight-through processing and a point of trade guarantee. In that paper, GSCC explained that an earlier deadline is necessary to ensure that its members have enough time to reconcile all their activity by the end of the processing day. GSCC also announced its plans to move the submission deadline from 10:00 p.m. to 8:00 p.m. in its Interactive Messaging and Real-time Comparison New Service Bulletin distributed to members in December 1999 and in the Interactive Messaging Participant Specifications in February 2000.

On June 2, 2000, GSCC informed its members by an Important Notice that in preparation for the planned implementaiton of real-time comparison services members should begin submitting trade data to GSCC by 8:00 p.m. on July 10, 2000. GSCC members have thus had the opportunity to make all necessary system and other internal changes in order to accommodate the earlier deadline and to become accustomed to it. GSCC has strongly encouraged all members to abide by the 8:00 p.m. deadline but has not enforced the deadline.

GSCC will now formally adopt the 8:00 p.m. trade submission deadline and impose a fine schedule for late trade submission to enforce the deadline. The earlier submission deadline is one of the first steps to accomplish GSCC's plan to move to real-time interactive messaging and T+0 settlement. The move to the earleir submission deadline is also an important measure that will allow GSCC members to become accustomed to submitting trade data earlier in the day. After full implementation of the interactive messaging process, GSCC may ultimately establish an even earlier submission deadline in accordance with future business developments and market practices.[3] Finally, the earlier submission deadline supports GSCC's cross-margining initiatives with other clearing corporations, including those in Europe, as earlier submission will facilitate close coordination of data transfer among clearing corporations across multiple time zones.

GSCC's new fine schedule closely tracks its old fine schedule concerning late payments of funds settlement debits and late satisfactions of clearing fund deficiency calls. Like the old fine schedule, the new schedule provides a warning mechanism before any fine is imposed. In addition, the dollar amounts of the fines in the new schedule are similar to those in the old schedule.

II. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and particularly with the requirements of section 17A(b)(3)(F)[4] of the Act. Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. The Commission finds that GSCC's rule change meets this requirment because GSCC will now be able to prepare and its members will be able to view their comparison results at an earlier time thereby affording GSCC members more time to reconcile their trading activity before the end of the processing day. In addition, the earlier trade submission deadline should support GSCC's future initiatives, such as real-time processing, which should further GSCC's ability to provide for the prompt and accurate clearance and settlement of securities transactions. Finally, the imposition of the fine schedule is necessary for GSCC to promote and enforce full compliance with the earlier submission deadline.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–GSCC–00–09) be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29197 Filed 11–21–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45060; File No. SR–Phlx–2001–25]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to the Exchange's Auto-Quote System

November 15, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 5, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Phlx. The Phlx submitted amendments to the proposed rule change on August 29,

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 44708 (Aug. 15, 2001), 66 FR 44192.

[3] GSCC will soon be actively encouraging members to submit trade data in real-time and might ultimately establish an even earlier submission deadline in accordance with future business developments and market practices.

[4] 15 U.S.C. 78q–1(b)(3)(F).

[5] 17 CFR 200.30–3(a)(12)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

2001 [3] and October 31, 2001.[4] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend Commentary .01 to Exchange Rule 1080, Philadelphia Stock Exchange Automated Options Market (''AUTOM'') and Automated Execution System (''AUTO–X''), to add language providing an enhanced description of Auto-Quote, the Exchange's electronic options pricing system and to permit the specialist to consult with the trading crowd in setting Auto-Quote parameters. The proposed language would be set forth in new subsection (b) of the Commentary .01. The text of the proposed rule change is set forth below. New language is in italics. Deletions are in brackets.

Rule 1080. Philadelphia Stock Exchange Automated Options Market (AUTOM) and Automatic Execution System (AUTO–X)

(a)–(j) No change.

Commentary:

.01

(a) Automatic Quotation (Auto-Quote) is the Exchange's electronic options pricing system, which enables specialists to automatically monitor and instantly update quotations.

(b)(i) The Auto-Quote System includes three commonly used options pricing algorithms: the Black Scholes Option Pricing Model; the Cox, Ross and Rubenstein Binomial Option Pricing Model; and the Barone, Adesi and Whaley American Option Pricing Model. In addition, a specialist may separately employ other pricing models, by establishing a specialized connection by-passing the Exchange's Auto-Quote System, which is known as a specialized quote feed.

(ii) Specialists determine which model to select per option and may change models during the trading day. Each pricing model requires the specialist to input various parameters, such as interest rates, volatilities (delta, vega, theta, gamma, etc.) and dividends. The specialist may, but is not required to (a) consult with and/or (b) agree with the trading crowd in setting these parameters or selecting a model, but the members of the trading crowd are not required to provide input in these decisions, and in all cases, the specialist has the responsibility and authority to make the final determination.

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to codify a description of the Exchange's Auto-Quote system, which electronically prices options, and to permit the specialist to consult with the trading crowd in setting Auto-Quote parameters. On September 11, 2000, the Commission issued an order [5] that requires the options exchanges to adopt new, or amend existing, rules to include any practice or procedure, not currently authorized by rule, whereby market makers determine by agreement the spreads or option prices at which they will trade any option, or the allocation of orders in that option.[6] This proposed rule change is being submitted pursuant to this undertaking.

Currently, Exchange Rule 1080 governs the operation of AUTOM, the Exchange's automated order routing, delivery, execution and reporting system for options. Auto-Quote, one feature of AUTOM, is currently defined in Commentary .01 as the Exchange's electronic options pricing system, which enables specialists to automatically monitor and instantly update quotations.

Phlx option quotations are maintained and updated electronically through Auto-quote, which generates automatic pricing of all option series and allows modification of pricing models to guarantee accurate reflection of option prices based on the value of the underlying stock. Auto-Quote also facilitates dissemination of improving bid/offer prices for orders entered through AUTOM. Auto-Quote provides for the dissemination of appropriate and accurate prices through automatic updating.

The proposed rule change incorporates a more thorough description of Auto-Quote into Exchange rules. First, it describes its various pricing models, inputs, and parameters. Second, it provides that specialists may establish a specialized proprietary connection (''specialized quote feed'') that by-passes the Auto-Quote system. Finally, it provides that while the specialist selects the pricing model and inputs for Auto-Quote, he or she may (but is not required to and may, for proprietary business reasons, determine not to) consult with the trading crowd on the pricing model and the inputs to be used.[7] The proposed rule change also provides that if the specialist consults with one member of the crowd, all members of the crowd present must be given the opportunity to provide input.[8] However, members of the trading crowd would not be required

[3] Letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated August 28, 2001 (''Amendment No. 1''). Among other things, Amendment No. 1: (i) States the reasons why a specialist would wish to consult with the trading crowd about specific Auto-Quote parameters; (ii) clarifies that if a specialist decides to consult with one member of the trading crowd about the Auto-Quote parameters, all members of the crowd that are present at the time must be given the opportunity to consult; and (iii) revises proposed Commentary .01(b)(ii) to Phlx Rule 1080 to state that the specialist may determine which model to select per option, not per series, as previously stated.

[4] Letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated October 30, 2001 (''Amendment No. 2''). Amendment No. 2 revises the text of proposed Commentary .01(b)(ii) to Phlx Rule 1080 to clarify that where the specialist determines to consult with and/or agree with the trading crowd with respect to selecting the Auto Quote System model or setting the parameters, members of the trading crowd are not required to provide input to the specialist about these decisions.

[5] *See* Order Instituting Public Administrative Proceedings Pursuant to Section 19(h)(1) of the Securities Exchange Act of 1934, Making Findings and Imposing Remedial Sanctions. Securities Exchange Act Release No. 43268 (September 11, 2000) (''Order'').

[6] *See* Section IV.B.j. of the Order.

[7] This new language is being proposed inasmuch as the specialist's consultation with market makers on the pricing model and Auto Quote parameters could be viewed as determining option prices by agreement for purposes of the Order and is therefore required by the Order to be provided for in Exchange rules. The specialist may elect to discuss the pricing model with market makers for any reason, including as a check against possible error in use of the model. The specialist also may determine that such discussions are appropriate in view of the fact that the disseminated quote is deemed to be the quote of the ROTs in the crowd, unless the ROT clearly and audibly communicates, on a timely basis, an intent to adopt a different quote. *See* Phlx Rule 1080, Commentary .01(c).

[8] *See* Amendment No. 1, *supra* note 3.

to provide input to the specialist in setting Auto-Quote parameters.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act [10] in general and furthers the objectives of section 6(b)(5) [11] in particular in that it is designed to promote just and equitable principles of trade, remove impediments to a free and open market and a national market system, and protect investors and the public interest by clarifying and describing Auto-Quote, including the specialized quote feed, in Exchange rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Phlx did not solicit or receive written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Phlx consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filings will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to the File No. SR–Phlx–2001–25 and should be submitted by December 14, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29248 Filed 11–21–01; 8:45 am]

BILLING CODE 8010–01–M

[9] *See* Amendment No. 2, *supra* note 4.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Notice of Teleconference

AGENCY: Social Security Administration (SSA).

ACTION: Notice of teleconference.

DATES: December 12, 2001, 1 PM—4 PM (ET)

ADDRESSES: Ticket to Work and Work Incentives Advisory Panel Office, Social Security Administration, 400 Virginia Avenue, SW, Suite 700, Washington, DC 20024.

Teleconference: Wednesday, December 12, 2001, 1 PM—3 PM (ET); Ticket to Work and Work Incentives Advisory Panel Conference Call; Call-in number: 1–800–857–2846; Pass code: 12211; Leader/Host: Sarah Mitchell Wiggins.

SUPPLEMENTARY INFORMATION: *Type of meeting:* This teleconference meeting is open to the public. The interested public is invited to participate by coming to the address listed above or calling into the teleconference. Public testimony will not be taken.

Purpose: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Social Security Administration (SSA) announces this teleconference meeting of the Ticket to Work and Work Incentives Improvement Act (TWWIIA) Advisory Panel (the Panel). Section 101(f) of Public Law 106–170 establishes the Panel to advise the Commissioner of SSA, the President, and the Congress on issues related to work incentives programs, planning and assistance for individuals with disabilities as provided under section 101(f)(2)(A) of the TWWIIA. The Panel is also to advise the Commissioner on matters specified in section 101(f)(2)(B) of that Act, including certain issues related to the Ticket to Work and Self-Sufficiency Program established under section 101(a) of that Act.

Agenda: The Panel will deliberate on the implementation of TWWIIA, conduct committee activities and administrative business. The agenda for this meeting will be posted on the Internet at *http://www.ssa.gov/work/panel/* one week prior to the teleconference or can be received in advance electronically or by fax upon request. Records are being kept of all Panel proceedings and will be available for public inspection by appointment at the Panel office.

Contact Information: Anyone requiring information regarding the Panel should contact the TWWIIA Panel staff by mail addressed to Ticket to Work and Work Incentives Advisory Panel Staff, Social Security Administration, 400 Virginia Avenue, SW., Suite 700, Washington, DC, 20024, telephone contact with Kristen Breland at (202) 358–6430, fax at (202) 358–6440 or e-mail to *TWWIIAPanel@ssa.gov*

Dated: November 16, 2001.

Deborah M. Morrison,

Designated Federal Officer.

[FR Doc. 01–29285 Filed 11–21–01; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

[Public Notice 3846]

Discretionary Grant Programs Application Notice Establishing Closing Date for Transmittal of Certain Fiscal Year 2002 Applications

AGENCY: Department of State.

SUMMARY: The Department of State invites applications from national organizations with interest and expertise in conducting research and training to serve as intermediaries administering national competitive programs concerning the countries of Central and East Europe and Eurasia. The grants will be awarded through an open, national competition among applicant organizations.

Authority for this Program for Research and Training on Eastern Europe and the Independent States of the Former Soviet Union is contained in the Soviet-Eastern European Research

and Training Act of 1983 (22 U.S.C. 4501–4508, as amended).

The purpose of this application notice is to inform potential applicant organizations of fiscal and programmatic information and closing dates for transmittal of applications for awards in Fiscal Year 2002 under a program administered by the Department of State. The program seeks to build and sustain expertise among Americans willing to make a career commitment to the study of Central and East Europe and the NIS.

Organization of Notice: This notice contains three parts. Part I lists the closing date covered by this notice. Part II consists of a statement of purpose and priorities of the program. Part III provides the fiscal data for the program.

Part I

Closing Date for Transmittal of Applications

An application for an award must be mailed or hand-delivered by February 8, 2002.

Applications Delivered by Mail

An application sent by mail must be addressed to Kenneth E. Roberts, Executive Director, Advisory Committee for Studies of Eastern Europe and the Independent States of the Former Soviet Union, INR/RES, Room 2251, U.S. Department of State, 2201 C Street, NW., Washington, DC 20520–6510.

An applicant must show proof of mailing consisting of *one* of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial center.

(4) Any other proof of mailing acceptable to the Department of State.

If any application is sent through the U.S. Postal Service, the Department of State does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

An applicant should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with the local post office.

An applicant is encouraged to use registered or at least first class mail. Late applications will not be considered and will be returned to the applicant.

Applications Delivered by Hand

An application that is hand delivered must be taken to Kenneth E. Roberts, Executive Director, Advisory Committee for Studies of Eastern Europe and the Independent States of the Former Soviet Union, INR/RES, Room 2251, 2201 C Street, NW., Washington, DC. Please phone first at (202) 736–4572 to gain access to the building.

The Advisory Committee staff will accept hand-delivered applications between 9:00 a.m. and 4:00 p.m. EST daily, except Saturdays, Sundays, and Federal holidays.

An application that is hand delivered will not be accepted after 4:00 p.m. on the closing date.

Part II

Program Information

In the Soviet-Eastern European Research and Training Act of 1983, the Congress declared that independently verified factual knowledge about the countries of that area is ''of utmost importance for the national security of the United States, for the furtherance of our national interests in the conduct of foreign relations, and for the prudent management of our domestic affairs.'' Congress also declared that the development and maintenance of such knowledge and expertise ''depends upon the national capability for advanced research by highly trained and experienced specialists, available for service in and out of Government.'' The program provides financial support for advanced research, training and other related functions on the countries of the region. By strengthening and sustaining in the United States a cadre of experts on Central and East Europe and the NIS, the program contributes to the overall objectives of the FREEDOM Support and SEED Acts.

The full purpose of the Act and the eligibility requirements are set forth in Public Law 98164, 97 Stat. 1047–50, as amended. The countries include Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Former Yugoslav Republic of Macedonia, Georgia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Poland, Romania, Russia, the Former Yugoslavia (including Serbia, Kosovo, and Montenegro), Slovakia, Slovenia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.

The Act establishes an Advisory Committee to recommend grant policies and recipients. The Secretary of State, after consultation with the Advisory Committee, approves policies and makes the final determination on awards.

Applications for funding under the Act are invited from U.S. organizations prepared to conduct competitive programs on Central and East Europe and the NIS and related fields. Applying organizations or institutions should have the capability to conduct competitive award programs that are national in scope. Programs of this nature are those that make awards based upon an open, nationwide competition, incorporating peer group review mechanisms. Individual end-users of these funds—those to whom the applicant organizations or institutions propose to make awards—must be at the graduate or post-doctoral level, and must have demonstrated a likely career commitment to the study of Central and East Europe and/or the NIS.

Applications sought in this competition among organizations or institutions are those that would contribute to the development of a stable, long-term, national program of unclassified, advanced research and training on the countries of Central and East Europe and/or the NIS by proposing:

(1) *National programs* which award contracts or grants to American institutions of higher education or not-for-profit corporations in support of post-doctoral or equivalent level research projects, such contracts or grants to contain shared-cost provisions;

(2) *National programs* which offer graduate, post-doctoral and teaching fellowships for advanced training on the countries of Central and East Europe and the NIS, and in related studies, including training in the languages of the region, with such training to be conducted on a shared-cost basis, at American institutions of higher education;

(3) *National programs* which provide fellowships and other support for American specialists enabling them to conduct advanced research on the countries of Central and East Europe and the NIS, and in related studies; and those which facilitate research collaboration between Government and private specialists in these areas;

(4) *National programs* which provide advanced training and research on a reciprocal basis in the countries of Central and East Europe and the NIS by facilitating access for American specialists to research facilities and resources in those countries;

(5) *National programs* which facilitate the public dissemination of research methods, data and findings; and those which propose to strengthen the national capability for advanced research or training on the countries of

Central and East Europe and the NIS in ways not specified above.

Note: The Advisory Committee will not consider applications from individuals to further their own training or research, or from institutions or organizations whose proposals are not for competitive award programs that are national in scope as defined above. Support for specific activities will be guided by the following policies and priorities:

• Support for Transitions. The Advisory Committee strongly encourages support for research activities which, while building expertise among US specialists on the region, also: (1) Promote fundamental goals of US assistance programs such as helping establish market economies and promoting democratic governance and civil societies, and (2) provide knowledge to both US and foreign audiences related to current US policy interests in the region, broadly defined. This includes, but is not limited to, such topics as resolution of ethnic, religious, and other conflicts; terrorism; trafficking in persons, transition economics; media studies; women's issues; human rights; and citizen participation in politics and civil society. For on-site research, applicants are encouraged to think creatively about how individuals' work may complement democratization and marketization assistance activities in the region. Examples might include lecturing at a university or participating in workshops with host government and parliamentary officials, nongovernmental organizations, and other assistance target audiences on issues related to market and democratic transitions.

For the Eurasian region, the Advisory Committee will give priority to programs that focus resources on Central Asia and the Caucasus with a particular emphasis on issues related to ethnic and religious conflict. For Central and Eastern Europe, the Advisory Committee will give priority to programs that focus on the Balkans, especially the former Yugoslavia. Historical or cultural research that promotes understanding of current events in the region also may be funded if an explicit connection can be made to contemporary political and/or economic transitions.

• *Publications.* Funds awarded in this competition should not be used to subsidize journals, newsletters and other periodical publications except in special circumstances, in which cases the funds should be supplied through peer-review organizations with national competitive programs.

• *Conferences.* Proposals for conferences, like those for research projects and training programs, should be assessed according to their relative contribution to the advancement of knowledge and to the professional development of cadres in the fields. Therefore, requests for conference funding should be directed to one or more of the national peer-review organizations receiving program funds, with proposed conferences being evaluated competitively against research, fellowship or other proposals for achieving the purposes of the grant.

• *Library Activities.* Funds may be used for certain library activities that clearly strengthen research and training on the countries of Central and East Europe and the NIS and benefit the fields as a whole. Such programs must make awards based upon open, nationwide competition, incorporating peer group review mechanisms. Funds may not be used for activities such as modernization, acquisition, or preservation. Modest, cost-effective proposals to facilitate research, by eliminating serious cataloging backlogs or otherwise improving access to research materials, will be considered.

• *Language Support.* The Advisory Committee encourages attention to the non-Russian languages of Eurasia and the less commonly taught languages of Central and East Europe. Support provided for Russian language instruction/study normally will be only for advanced level. Applicants proposing to offer language instruction are encouraged to apply to a national program as described above that has appropriate peer group review mechanisms.

• *Support for Non-Americans.* The purpose of the program is to build and sustain U.S. expertise on the countries of Central and East Europe and the NIS. Therefore, the Advisory Committee has determined that highest priority for support always should go to American specialists (i.e., U.S. citizens or permanent residents). Support for such activities as long-term research fellowships, i.e., nine months or longer, should be restricted solely to American scholars. Support for short-term activities also should be restricted to Americans, except in special instances where the participation of a non-American scholar has clear and demonstrable benefits to the American scholarly community. In such special instances, the applicant must justify the expenditure. Despite this restriction on support for non-Americans, collaborative projects are encouraged—where the non-American component is funded from other sources—and priority is given to institutions whose programs contain such an international component.

• *Balanced National Program.* In making its recommendations, the Committee will seek to encourage a coherent, long-term, and stable effort directed toward developing and maintaining a national capability on the countries of Central and East Europe and the NIS. Program proposals can be for the conduct of any of the functions enumerated, but in making its recommendations, the Committee will be concerned to develop a balanced national effort that will ensure attention to all the countries of the area.

• *Cost-sharing.* Legislation requires and this announcement indicates under *Program Information* of this section that in certain cases grantee organizations must include shared-cost provisions in their arrangements with end-users. Cost-sharing is encouraged, whenever feasible, in all programs.

Part III

Available Funds

Awards are contingent upon the availability of funds. In Fiscal Year 2001, the program was funded with $4.197 million from the FREEDOM Support and Support for East European Democracy (SEED) Acts, which funded grants to 9 national organizations, with $2.7 million for activities on the NIS and $1.497 million for those on Central and East Europe, including the Baltic states. The number of awards varies each year, depending on the level of funding and the quality of the applications submitted. The level of funding in Fiscal Year 2002 is not yet determined.

The Department legally cannot commit funds that may be appropriated in subsequent fiscal years. Thus multi-year projects cannot receive assured funding unless such funding is supplied out of a single year's appropriation. Grant agreements may permit the expenditure from a particular year's grant to be made up to three years after the grant's effective date.

Applications

Applications must be prepared and submitted in 20 copies in 12 pitch in the following format: one-page, single-spaced Executive Summary; Budget presentation; narrative description of proposed programs not to exceed 20 double-spaced pages; one-page, single-spaced vitae of key professional staff; and required certifications. Applicants may append other information they consider essential, although bulky submissions are discouraged and run the risk of not being reviewed fully.

Budget

Because funds will be appropriated separately for Central and East Europe (including the Baltic states) and Eurasia, proposals must indicate how the requested funds will be distributed by region, country (to the extent possible), and activity. Subsequently, grant recipients must report expenditures by region, country, and activity.

Applicants should familiarize themselves with Department of State grant regulations contained in 22 CFR part 145, ''Grants and Cooperative Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations''; 22 CFR part 137, ''Department of State Government-wide Debarment and Suspension (Non-Procurement) and Government-wide Requirements for Drug-Free Workplace (Grants)''; OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations''; and OMB Circular A–133, ''Audits of Institutions of Higher Learning and Other Non-Profit Institutions''; and indicate or provide the following information:

(1) Whether the organization falls under OMB Circular No. A–21, ''Cost Principles for Educational Institutions,'' or OMB Circular No. A–122, ''Cost Principles for Nonprofit Organizations;''

(2) A detailed program budget indicating direct expenses with clearly identified administrative costs by program element and by region (NIS or Central and East Europe), indirect costs, and the total amount requested. The budget should indicate clearly the total amount requested as a sum of the amount requested for NIS activities plus the amount requested for Central and East Europe activities. The budget also should reflect administrative costs as a percentage of the total requested funding. NB: Indirect costs are limited to 10 percent of total direct program costs. Applicants requesting funds to supplement a program having other sources of support should submit a current budget for the total program and an estimated future budget for it, showing how specific lines in the budget would be affected by the allocation of requested grant funds. Other funding sources and amounts, when known, should be identified.

(3) The applicant's cost-sharing proposal, if applicable, containing appropriate details and cross references to the requested budget;

(4) The organization's most recent audit report (the most recent U.S. Government audit report, if available) and the name, address, and point of contact of the audit agency. N.B.: The threshold for grants that trigger an audit requirement has been raised from $25,000 to $300,000.

(5) An indication of the applicant's priorities if funding is being requested for more than one program or activity.

All payments will be made to grant recipients through the Department of State.

Narrative Statement

The Applicant must describe fully the proposed programs, including detailed information about plans for advertising programs, peer review and selection procedures and identification of anticipated selection committee participants, estimates of the types and amounts of anticipated awards, and benefits of these programs for the Central and East European, Russian, and Eurasian fields.

Applicants who have received previous grants from this State Department program should provide detailed information on the end-user awards made, including, where applicable, names/affiliations of recipients, and amounts and types of awards. Applicants should specify both past and anticipated applicant to award ratios. A summary of an organization's past grants under this State Department program also should be included.

Proposals from national organizations involving language instruction programs should provide, for those programs supported in the past year, information on the criteria for evaluation, including levels of instruction, degrees of intensiveness, facilities, methods for measuring language proficiency (including pre- and post-testing), instructors' qualifications, and budget information showing estimated costs per student.

Certifications

Applicants must include a description of affirmative action policies and practices and certifications of compliance with the provisions of: (1) The Drug-Free Workplace Act (Pub. L.100–690), in accordance with Appendix C of 22 CFR part 137, subpart F; and (2) section 319 of the Department of the Interior and Related Agencies Appropriations Act (Pub. L. 101–121), in accordance with Appendix A of 22 CFR part 138, New Restrictions on Lobbying Activities.

Technical Review

The Advisory Committee for Studies of Eastern Europe and the Independent States of the Former Soviet Union will evaluate applications on the basis of the following criteria:

(1) Responsiveness to the substantive provisions set forth above in Program Part II, Information (45 points);

(2) The professional qualifications of the applicant's key personnel and selection committees, and their experience conducting national competitive award programs of the type the applicant proposes on the countries of Central and East Europe and/or the NIS (35 points); and

(3) Budget presentation and cost effectiveness (20 points).

Further Information

For further information, contact Kenneth E. Roberts, Executive Director, Advisory Committee for Studies of Eastern Europe and the Independent States of the Former Soviet Union, INR/RES, Room 2251, U.S. Department of State, 2201 C Street, NW., Washington, DC 20520–6510. Telephone: (202) 736–4572 or 736–4386, fax: (202) 736–4851 or (202) 736–4557.

Dated: November 15, 2001.

Kenneth E. Roberts,

Executive Director, Advisory Committee for Studies of Eastern Europe and the Independent States of the Former Soviet Union, Department of State.

[FR Doc. 01–29279 Filed 11–21–01; 8:45 am]

BILLING CODE 4710–32–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2001–10982]

Towing Safety Advisory Committee; vacancies

AGENCY: Coast Guard, DOT.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Towing Safety Advisory Committee (TSAC). TSAC provides advice and makes recommendations to the Department of Transportation on matters relating to shallow-draft inland and coastal waterway navigation and towing safety.

DATES: Application forms should reach us on or before May 17, 2002.

ADDRESSES: You may request an application form by writing to TSAC Application; Commandant (G–MSO–1), Room 1210; U.S. Coast Guard; 2100 Second Street SW.; Washington, DC 20593–0001; by calling 202–267–0229; or by faxing 202–267–4570. Send your original completed and signed application in written form to the above

street address. This notice is available on the Internet at *http://dms.dot.gov* and the application form is available at *http://www.uscg.mil/hq/g-m/advisory/index.htm*

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Miante; Assistant Executive Director of TSAC, telephone 202–267–0229, fax 202–267–4570, or e-mail gmiante@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION: The Towing Safety Advisory Committee (TSAC) is a Federal advisory committee under 5 U.S.C. App. 2. It advises the Secretary of Transportation on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States in advance of meetings of the International Maritime Organization.

TSAC meets at least once a year at Coast Guard Headquarters, Washington, DC, or another location selected by the Coast Guard. It may also meet for extraordinary purposes. Its working groups may meet to consider specific problems as required. We will consider applications for five positions that expire or become vacant in September 2002 as follows: two members from the barge and towing industry, reflecting a geographical balance; one member from port districts, authorities, or terminal operators; one member from maritime labor; and one member from the general public. To be eligible, applicants should have experience in towing operations, marine transportation, occupational safety and health, environmental protection, or business operations associated with the towing or maritime industry. Each member serves for a term of 3 years. A few members may serve consecutive terms. All members serve at their own expense and receive no salary, reimbursement of travel expenses, or other compensation from the Federal Government.

In support of the policy of the Department of Transportation on gender and ethnic diversity, we encourage qualified women and members of minority groups to apply.

If you are selected as a member who represents the general public, we will require you to complete a Confidential Financial Disclosure Report (OGE Form 450). We may not release the report or the information in it to the public, except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a).

Dated: November 14, 2001.

Joseph J. Angelo,

Director of Standards, Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 01–29265 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–91]

Petitions for Exemption; Summary of Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of dispositions of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, Sandy Buchanan-Sumter (202) 267–7271, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC on November 19, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: FAA–2001–10796.

Petitioner: Kendall Flying Service.

Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).

Description of Relief Sought/Disposition: To permit KFS to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed in this aircraft.

Grant, 10/19/2001, Exemption No. 7648

Docket No.: FAA–2001–9946.

Petitioner: Mr. Tom Travis.

Section of 14 CFR Affected: 14 CFR § 121.383(c).

Description of Relief Sought/Disposition: To permit Mr. Travis to act as a pilot in operations conducted under part 121 after reaching his 60th birthday.

Denial, 10/19/2001, Exemption No. 7649.

Docket No.: FAA–2001–10814 (previously Docket No. 28317).

Petitioner: Eagle Canyon Airlines, Inc., dba Scenic Airlines.

Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).

Description of Relief Sought/Disposition: To permit ECA to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed in those aircraft.

Grant, 10/19/2001, Exemption No. 7147A.

Docket No.: FAA–2001–10717 (previously Docket No. 29723).

Petitioner: Westjet Air Center, Inc.

Section of 14 CFR Affected: 14 CFR § 61.3(a) and (c).

Description of Relief Sought/Disposition: To permit Westjet pilots to carry written confirmation of FAA issued pilot or medical certificates provided by Westjet based on information in Westjet's approved record system.

Grant, 10/22/2001, Exemption No. 7136A.

Docket No.: FAA–2001–10284 (previously Docket No. 20049).

Petitioner: T.B.M., Inc.

Section of 14 CFR Affected: 14 CFR § 91.529(a)(1).

Description of Relief Sought/Disposition: To permit TBM to operate its McDonnell Douglas DC–6 and DC–7 aircraft without a flight engineer during flightcrew training, ferry operations, and test flights conducted to prepare for firefighting operations conducted under 14 CFR part 137.

Grant, 10/22/2001, Exemption No. 2956L.

Docket No.: FAA–2001–9944.

Petitioner: Schwartz Engineering Co.

Section of 14 CFR Affected: 14 CFR § 25.813(e).

Description of Relief Sought/Disposition: To permit Schwartz to install interior doors between passenger compartments on Boeing Model 757–200 S/N 28463.

Grant, 10/19/2001, Exemption No. 7651.

Docket No.: FAA–2001–9943.

Petitioner: Schwartz Engineering Co.

Section of 14 CFR Affected: 14 CFR § 25.813(e).

Description of Relief Sought/Disposition: To permit Schwartz to install interior doors between passenger compartments on Boeing Model 767–200 S/N 28270.

Grant, 10/19/2001, Exemption No. 7650.

[FR Doc. 01–29261 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–90]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before December 13, 2001.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF building at the Department of Transportation at the above address. Also you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, Sandy Buchanan-Sumter (202) 267–7271, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on November 19, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: FAA–2001–10362.
Petitioner: Alpine Aviation, Inc. dba Alpine Air.
Section of 14 CFR Affected: 14 CFR § 61.51(e).
Description of Relief Sought: To permit certain Alpine Air second-in command (SIC) pilots who perform ''the duties of pilot in command (PIC) under the supervision of a qualified PIC'' to log their flight time in Beechcraft 99 and 1900 airplanes as PIC flight time. These SIC pilots would be permitted to log their time as PIC flight time even though (1) more than one pilot is not required by either the airplane type certificate or the regulations under which the flight is conducted, and (2) the SIC pilot does not hold the required type rating for the Beechcraft 1900 airplane.
Docket No.: FAA–2001–10873.
Petitioner: Air Serv International.
Section of 14 CFR Affected: Special Federal Aviation Regulation No. 90.
Description of Relief Sought: To permit Air Serv to provide humanitarian relief flights into the territory and airspace of Afghanistan.

[FR Doc. 01–29262 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–89]

Petitions for Exemption; Summary of Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of dispositions of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, Sandy Buchanan-Sumter (202) 267–7271, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC on November 19, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: FAA–2001–10231.
Petitioner: GE VARIG.
Section of 14 CFR Affected: 14 CFR § 145.47(b).
Description of Relief Sought/Disposition: To permit GE VARIG to use the calibration standards of the Instituto Nacional de Metrologia, Normalizacao e Qualidade Industrial in lieu of the calibration standards of the U.S. National Institute of Standards and Technology to test its inspection and test equipment.
Grant, 10/24/2001, Exemption No. 6709B.
Docket No.: FAA–2001–102363.
Petitioner: Gulfstream Aerospace Services Corporation.
Section of 14 CFR Affected: 14 CFR § 43.9(a)(4), 43.11(a)(3, appendix B to part 43, and § 145.57(a).
Description of Relief Sought/Disposition: To permit Gulfstream qualified technicians and inspection personnel to use electronic signatures in lieu of physical signatures to satisfy approval for return-to-service requirements.
Grant, 10/24/2001, Exemption No. 7653.
Docket No.: FAA–2001–10733 (previously Docket No. 29799).
Petitioner: Bombardier Aerospace, Learjet, Inc.
Section of 14 CFR Affected: 14 CFR § 145.45(f).
Description of Relief Sought/Disposition: To permit Bombardier to place an adequate number of repair station Inspection Procedures Manuals (IPM) in inspection areas and to assign IPMs to key individuals.
Grant, 10/24/2001, Exemption No. 7114A.
Docket No.: FAA–2001–10469.
Petitioner: United Airlines.
Section of 14 CFR Affected: 14 CFR § 145.45(f).
Description of Relief Sought/Disposition: To permit United to make available to all of its supervisory and inspection personnel one copy of its repair inspection procedures manual, rather than giving a copy of the manual to each of these individuals.
Grant, 10/24/2001, Exemption No. 6393C.
Docket No.: FAA–2001–10415.
Petitioner: Wiggins Airways, Inc.
Section of 14 CFR Affected: 14 CFR § 21.197(c)(2).
Description of Relief Sought/Disposition: To permit Wiggins to receive a special flight permit with continuing authorization to conduct ferry flights on its aircraft with nine or fewer passenger seats.
Denial, 10/24/2001, Exemption No. 7654.
Docket No.: FAA–2001–10480.
Petitioner: Business Jet Center, Ltd.
Section of 14 CFR Affected: 14 CFR § 125.226(b)(1).

Description of Relief Sought/Disposition: To permit Business Jet Center, Ltd., to operate one British Aerospace BAC One-Eleven (BAC 1–11) 410AQ airplane, serial No. 054, and one BAC 1–11 419EP airplane, serial No. 120, under part 125 without an approved digital flight data recorder installed.

Grant, 10/17/2001, Exemption No. 7655.

Docket No.: FAA–2001–9687.

Petitioner: Pacific Helicopter Tours, Inc.

Section of 14 CFR Affected: 14 CFR § 135.152(a).

Description of Relief Sought/Disposition: To permit PHT to operate two Bell 212 helicopters and four Sikorsky S–61N helicopters (Serial Nos. 61364, 61488, 61771, and 61821) under part 135 without each of those helicopters being equipped with an approved digital flight data recorder.

Grant, 10/22/2001, Exemption No. 7257B.

[FR Doc. 01–29263 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Terminal Area Operations Aviation Rulemaking Committee

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of public meeting.

SUMMARY: This document announces the location of a public meeting in which the Federal Aviation Administration (FAA) and other interested parties will discuss the draft charter, tasking, and organization of the proposed Terminal Area Operations Aviation Rulemaking Committee.

DATES: The public meeting will be held on December 5 and 6, 2001 at 9 a.m. Registration will begin at 8:30 a.m. on each day.

ADDRESSES: The public meeting will be held at the Dulles Airport Marriott, 45020 Aviation Drive, Dulles, VA 20166, (703) 471–9500.

People who plan to attend the meeting should contact Cindy Nordlie at *cindy,nordlie@faa.gov* or (202) 267–7627 no later than December 3, 2001. Please let Cindy Nordlie know if you plan to make a presentation at the meeting and if you need any audio-visual equipment for the presentation.

FOR FURTHER INFORMATION CONTACT: Questions regarding the logistics of the meeting should be directed to Ms. Cindy Nordlie, Airmen and Airspace Rules Division, ARM–108, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–7627, facsimile (202) 267–5075; e-mail: *cindy.nordlie@faa.gov.* Technical questions should be directed to Ms. Katherine Perfetti, Air Transportation Division, AFS–200, Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267–3760, facsimile (202) 267–5229; e-mail: *katherine.perfetti@faa.gov.*

SUPPLEMENTARY INFORMATION: On November 13, 2001, a Notice of Public Meeting was published in the **Federal Register** (66 FR 56897) announcing that this public meeting would be held in the Washington, DC area. The specific location of the public meeting was not published at that time. The meeting will be held at the Dulles Airport Marriott, 45020 Aviation Drive, Dulles, VA 20166, (703) 471–9500. For attendees who need to stay in a hotel, the following hotels, in addition to the Marriott listed above, are also near Washington Dulles International Airport: Hilton Washington Dulles Airport, (703) 478–2900; Hyatt Hotel-Dulles, (703) 713–1234; Fairfield Inn, 703–435–5300; Embassy Suites Dulles Airport, (703) 464–0200.

The purpose of the meeting is to discuss the draft charter, tasking, and organization of the proposed Terminal Area Operations Aviation Rulemaking Committee. An electronic copy of **Federal Register** notices, a draft of the charter, and other background information on the proposed Terminal Area Operations Aviation Rulemaking Committee can be found at the following Web site: *http://www.faa.gov/avr/arm/index.htm* under the ''Committees'' heading.

Participation at the Public Meeting

Requests from persons who wish to attend the public meeting should be received by the FAA no later than December 3, 2001. Please also let the FAA know if you plan to make a presentation at the meeting and if you need any audio-visual equipment for the presentation. Such requests should be submitted to Ms. Cindy Nordlie, Airmen and Airspace Rules Division, as listed in the section above titled **FOR FURTHER INFORMATION CONTACT.**

Background

Pursuant to the Administrator's authority under 49 U.S.C. 106(p)(5), the FAA is proposing to establish a Terminal Area Operations Aviation Rulemaking Committee. Safety issues and recommendations identified by the Commercial Aviation Safety Team (CAST) relating to Controlled Flight Into Terrain (CFIT) accidents and incidents, and airport capacity constraints with associated delays, dictate a need for improvements in terminal area operations. The capabilities of modern aircraft, specifically the use of area navigation (including the global positioning system), are not fully utilized. Evolving technologies and potential equipment upgrades provide increased operational and safety benefits not realized unless a practical means is established to facilitate implementation. The international aspects of aviation operation and aircraft production require that terminal area operational procedures and associated equipage be consistent.

The general goal of the committee will be to develop a means to implement improvements in terminal area operations that address safety, capacity, and efficiency objectives and that are consistent with international implementation. It will provide a forum for the FAA, other government entities, and the aviation industry to discuss issues, develop resolutions, and develop processes to facilitate the evolution of safe and efficient terminal area operations. This committee will support the international harmonization process.

To achieve these objectives, the committee's proposed initial task is to resolve outstanding issues pertaining to draft Advisory Circular (AC) 120–29A and other draft required navigation performance (RNP) materials including, but not limited to AC 20–RNP, AC 90–RNP RNAV, advisory Circular 120-xxx (airport obstacle analysis), and Order 8260.RNP.

Public Meeting Procedures

Persons who plan to attend the meeting should be aware of the following procedures established for this meeting:

1. There will be no admission fee or other charge to attend or to participate in the public meeting. The meeting will be open to all interested people who have confirmed attendance in advance or who register on the day of the meeting (between 8:30 a.m. and 9:00 a.m.), subject to availability of space in the meeting room.

2. Representatives from the FAA will conduct the public meeting.

3. The public meeting is intended as a forum to seek input to the draft charter, tasking, and organization of the proposed Terminal Area Operations Aviation Rulemaking Committee. Participants must limit their discussions to this issue.

4. The FAA will try to accommodate input from all attendees; therefore, it may be necessary to limit the discussion time available for an individual or group. If practicable, the meeting may be accelerated to enable adjournment in less than the time scheduled.

5. Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting.

6. Minutes of the meeting will be taken. The minutes and all material accepted by the FAA during the meeting will be included in TAOARC Web site at *http://www.faa.gov/avr/arm/index.htm* under the ''Committees'' heading.

7. The meeting is designed to seek public input on the draft charter, tasking, and organization of the proposed Terminal Area Operations Aviation Rulemaking Committee. Therefore, the meeting will be conducted in an informal and nonadversarial manner.

Issued in Washington, DC, on November 16, 2001.

Ava L. Mims,

Acting Director, Flight Standards Service.

[FR Doc. 01–29264 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; Los Angeles County, California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway widening project in the Cities of La Mirada, Norwalk, Downey and Santa Fe Springs in Los Angeles County, and the City of Buena Park in Orange County, California.

FOR FURTHER INFORMATION CONTACT: Cesar Perez, Senior Transportation Engineer, Federal Highway Administration, California Division, 980 Ninth Street, Suite 400, Sacramento, California 95814–2724, Telephone: (916) 498–5860.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the California Department of Transportation, will prepare an Environmental Impact Statement (EIS) on a proposal to improve Interstate Route 5 (I–5) in Los Angeles and Orange Counties, California. The proposed improvement is to widen the existing I–5 freeway, between State Route 91 (SR–91) and Interstate Route 605 (I–605), to add High Occupancy Vehicle (HOV) lanes and/or general purpose lanes. This project is the initial phase of the I–5 Ultimate HOV project, which proposes to widen I–5 between SR–91 in Orange County and I–710 in Los Angeles County. A Major Investment Study (MIS) for the project was completed July 1998. It identified a ten-lane facility as the locally preferred option.

The purpose of the proposed project is to (1) provide an improved level of service during the weekday AM and PM peak periods and to reduce congestion and enhance safety and mobility in this segment of the I–5 freeway as compared to the no-build condition; (2) provide continuity of facilities and capacity on the I–5 freeway between the SR–91 in Orange County and I–605 in Los Angeles County; (3) maintain flexibility in the freeway corridor for additional capacity improvements; (4) improve interchange access/egress points and levels of service; (5) improve access to regional transit and HOV facilities; (6) improve local surface streets to reduce existing and future congestion; and (7) explore Transportation System Management (TSM) improvements for the I–5 and parallel arterials.

Alternatives under consideration include (1) a no build option; (2) implementing a Transportation System Management/Transportation Demand Management plan; (3) enhancing transit; (4) constructing a 10-lane facility with two HOV lanes; and (5) constructing a 12-lane facility (may be constructed in stages depending on availability of funding) with two or four HOV lanes.

These basic alternatives will have additional design variations, which provide optional lane use (general, HOV, or auxiliary use), optional on and off ramp modifications, and other engineering details. A final selection of alternatives and their subset variations will not be made until all public and agency comments are reviewed following the Scoping process. **Note:** As required by the National Environmental Policy Act (NEPA), all other reasonable alternatives will be considered. These alternatives may be refined, combined various different alternative elements, or be removed from further consideration, as more analysis is conducted on the project alternatives.

Letters describing the proposed action and soliciting comments are being sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. Scoping meetings will be held on December 3 and 5, 2001 in La Mirada and Norwalk, respectively. Public notice will be given of the time and place of these meetings.

A series of public meetings will be held after the draft EIS is completed. Public notice will be given of the time and place of the meetings. The draft EIS will be available for public and agency review and comment prior to the formal public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposal action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: November 16, 2001.

Jeffrey W. Kolb,

Chief, District Operations-South, Sacramento, California.

[FR Doc. 01–29223 Filed 11–21–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8038–R

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8038–R, Request for Recovery of Overpayments Under Arbitrage Rebate Provisions.

DATES: Written comments should be received on or before January 22, 2002 to be assured of consideration.

ADDRESSES: Direct all written comments to George Freeland, Internal Revenue Service, room 5577, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue

Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Request for Recovery of Overpayments Under Arbitrage Rebate Provisions.

OMB Number: 1545–1750.

Form Number: 8038–R.

Abstract: Under Treasury Regulations section 1.148–3(i), bond issuers may recover an overpayment of arbitrage rebate paid to the United States under Internal Revenue Code section 148. Form 8038–R is used to request recovery of any overpayment of arbitrage rebate made under the arbitrage rebate provisions.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: State, local or tribal governments.

Estimated Number of Respondents: 200.

Estimated Time Per Respondent: 12 hours, 20 minutes.

Estimated Total Annual Burden Hours: 2,466.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 14, 2001.

George Freeland,

IRS Reports Clearance Officer.

[FR Doc. 01–29281 Filed 11–21–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 9460 and 9477

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Forms 9460 and 9477, Tax Forms Inventory Report.

DATES: Written comments should be received on or before January 22, 2002 to be assured of consideration.

ADDRESSES: Direct all written comments to George Freeland, Internal Revenue Service, room 5577, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Tax Forms Inventory Report.

OMB Number: 1545–1739.

Form Numbers: 9460 and 9477.

Abstract: Forms 9460 and 9477 are designed to collect tax forms inventory information from banks, post offices, and libraries that distribute federal tax forms. Data is collected detailing the quantities and types of tax forms remaining at the end of the filing season. The data is combined with the shipment date for each account and used to establish forms distribution guidelines for the following year. Form 9460 is used for accounts who order forms in carton quantities, and Form 9477 is used for those who order forms in less than carton quantities.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Reinstatement.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, and the Federal government.

Estimated Number of Respondents: 14,000.

Estimated Time Per Respondent: 14 minutes.

Estimated Total Annual Burden Hours: 3,417.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 13, 2001.

George Freeland,

IRS Reports Clearance Officer.

[FR Doc. 01–29282 Filed 11–21–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0128]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine eligibility to reinstate a veteran's Government Life Insurance policy.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 22, 2002.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0128'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or Fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles:

a. Notice of Lapse—Government Life Insurance, VA Form 29–389.

b. Application for Reinstatement, VA Form 29–389–1.

c. Notice of Past Due Payment, VA Form 29–389e.

OMB Control Number: 2900–0128.

Type of Review: Extension of a currently approved collection.

Abstract: The forms are used to inform veterans of their lapsed Government Life Insurance policy; application for reinstatement of insurance and notice of past due insurance payments.

Affected Public: Individuals or households.

Estimated Annual Burden: 4,943 hours.

a. VA Form 29–389—3,399 hours.

b. VA Form 29–389–1—1,060 hours.

c. VA Form 29–389e—484 hours.

Estimated Average Burden Per Respondent:

a. VA Form 29–389—12 minutes.

b. VA Form 29–389–1—10 minutes.

c. VA Form 29–389e—15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 25,288.

a. VA Form 29–389—16,993.

b. VA Form 29–389–1—6,359.

c. VA Form 29–389e—1,936.

Dated: November 7, 2001.

By direction of the Secretary.

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–29203 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0101]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements of eligibility verification reports.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 22, 2002.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0101'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or Fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501—3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles: Eligibility Verification Reports (EVR) (One EVR provides report instructions. Eleven EVRs are computer-generated forms that may be dispatched from VA's central computer. The remaining 11 forms (those with a ''-1'' suffix on the form number) are stocked forms).

a. Eligibility Verification Report Instructions, VA Form 21–0510.

b. Old Law Eligibility Verification Report (Surviving Spouse), VA Forms 21–0511S and 21–0511S–1.

c. Old Law Eligibility Verification Report (Veteran), VA Forms 21–0511V and 21–0511V–1.

d. Section 306 Eligibility Verification Report (Surviving Spouse), VA Forms 21–0512S and 21–0512S–1.

e. Section 306 Eligibility Verification Report (Veteran), VA Forms 21–0512V and 21–0512V–1.

f. Old Law and Section 306 Eligibility Verification Report (Children Only), VA Forms 21–0513 and 21–0513–1.

g. DIC Parent's Eligibility Verification Report, VA Forms 21–0514 and 21–0514–1.

h. Improved Pension Eligibility Verification Report (Veteran With No Children), VA Forms 21–0516 and 21–0516–1.

i. Improved Pension Eligibility Verification Report (Veteran With Children), VA Forms 21–0517 and 21–0517–1.

j. Improved Pension Eligibility Verification Report (Surviving Spouse With No Children), VA Forms 21–0518 and 21–0518–1.

k. Improved Pension Eligibility Verification Report (Child or Children), VA Forms 21–0519C and 21–0519C–1.

l. Improved Pension Eligibility Verification Report (Surviving Spouse With Children), VA Forms 21–0519S and 21–0519S–1.

OMB Control Number: 2900–0101.

Type of Review: Extension of a currently approved collection.

Abstract: The Eligibility Verification Reports are used to report changes in entitlement factors in VA's income-based benefit programs, pension and parents' Dependency and Indemnity Compensation (DIC). Any individual who has applied for or receives pension or parents' DIC must promptly notify VA in writing of any changes in entitlement factors.

The reports are also used to confirm that there have been no changes in entitlement factors.

Affected Public: Individuals or households.

Estimated Annual Burden: 146,947 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 293,894.

Dated: November 7, 2001.

By direction of the Secretary.

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–29204 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0130]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to securing information from holder's of VA-guaranteed loans regarding a loan to be foreclosed.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 22, 2002.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0130'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Status of Loan Account—Foreclosure or Other Liquidation, VA Form Letter 26–567.

OMB Control Number: 2900–0130.

Type of Review: Revision of a currently approved collection.

Abstract: The form letter is used to obtain information from holders of VA-guaranteed loans regarding a loan to be foreclosed. The information is used to specify the amount, if any, to be bid at the foreclosure sale.

Affected Public: Business or other for profit.

Estimated Annual Burden: 20,000 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 40,000.

Dated: November 7, 2001.

By direction of the Secretary:

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–29206 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–VHA2]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 24, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–VHA2.''

SUPPLEMENTARY INFORMATION:

Title: Study of Military Sexual Trauma Among the Reserve Components of the Armed Forces, VA Form 10–21052(NR).

OMB Control Number: 2900–VHA2.

Type of Review: New collection.

Abstract: The Veterans Millennium Health Care and Benefits Act mandates that the Secretary of Veterans Affairs, in consultation with the Secretary of Defense, will conduct a study to determine: (1) The extent to which former members of the Reserve Components of the Armed Forces experienced physical assault of a sexual nature or battery of a sexual nature while serving on active duty for training; (2) the extent to which such former members have sought counseling through VA relating to these incidents; and (3) the additional resources that, in the judgment of the Secretary, would be required to meet the projected need of these former members for such counseling.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on August 28, 2001, at pages 45372–45373.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,375 hours.

Estimated Average Burden Per Respondent: 45 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 4,500.

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–VHA2'' in any correspondence.

Dated: November 6, 2001.

By direction of the Secretary:

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–29207 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0393]

Agency Information Collection Activities Under OMB Review

AGENCY: Office of Acquisition and Materiel Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 et seq.), this notice announces that the Office of Acquisition and Materiel Management, Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 24, 2001.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Information Management Service (045A4), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030 or FAX (202) 273–5981 or e-mail to: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0393'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Veterans Affairs Acquisition Regulation (VAAR) part 813—Simplified Acquisition Procedures.

OMB Control Number: 2900–0393.

Type of Review: Reinstatement, with change, of a previously approved collection for which approval has expired.

Abstract: VA issues requests for quotations (RFQs) under procedures of the Federal Acquisition Regulation (FAR) part 13 and VAAR part 813 for the acquisition of goods and services necessary to operate the Department. In addition, VA requests information from vendors to establish blanket purchase agreements (BPAs). Any individual or business wishing to submit an offer on an RFQ or respond to a request to establish a BPA may do so. VA will use the information to determine which business or individual VA should issue a purchase order for the acquisition of goods or services or to determine which business or individual VA should establish a BPA. This collection of information covers only those acquisition-related actions conducted under the procedures of FAR part 13 and VAAR part 813 that affect 10 or more persons and are, therefore, subject to the PRA. Such actions include open market competitive acquisitions between $25,000 and $100,000 and, for commercial items, acquisitions between $100,000 and $5 million where simplified procedures are used.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on August 24, 2001, at page 44667.

Affected Public: Business or other for profit, individuals or households, not-for-profit institutions and state, local or tribal government.

Estimated Annual Burden: 10,650.

Estimated Average Burden Per Respondent: 1 hour.

Frequency of Response: On occasion.

Estimated Number of Respondents: 10,650.

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0393'' in any correspondence.

Dated: November 6, 2001.

By direction of the Secretary:

Barbara H. Epps,

Management Analyst, Information Management Service.

[FR Doc. 01–29208 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Illnesses Not Associated With Service in the Persian Gulf During the Persian Gulf War

AGENCY: Department of Veterans Affairs.

ACTION: Notice; clarification.

SUMMARY: In a notice published July 6, 2001 (66 FR 35702–35710), we stated in the **SUMMARY** paragraph, ''As required by law, the Department of Veterans Affairs (VA) hereby gives notice that the Secretary of Veterans Affairs, under the authority granted by the Persian Gulf War Veterans Act of 1998, Pub. L. 105–277, 112 Stat. 2681–742 through 2681–749 (codified at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Pub. L. 105–368, 112 Stat. 3315, has determined that there is no basis to establish a presumption of service connection for any disease based on service in the Persian Gulf during the Persian Gulf War.''

The purpose of this notice is to clarify that the September 7, 2000, National Academy of Sciences (NAS) report entitled ''Gulf War and Health, Volume 1. Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines'' covered only those items. This notice also is to clarify that VA's July 6, 2001, notice was intended to convey to the public that the Secretary of Veterans

Affairs, under the relevant statutory authorities, had determined only that, at that time, there was no basis for establishing a presumption of service connection for any illness suffered by Gulf War veterans based on exposure to depleted uranium, sarin, pyridostigmine bromide, and certain vaccines.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant or Bill Russo, Attorney-Advisor, Compensation and Pension Service, Regulations Staff, Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7213 and (202) 273–7211, respectively.

Anthony J. Principi,

Secretary of Veterans Affairs.

[FR Doc. 01–29209 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Professional Certification and Licensure Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the Professional Certification and Licensure Advisory Committee will meet at the Department of Veterans Affairs, Veterans Benefit Administration Conference Room 542, 1800 G St., NW, Washington, DC, on Monday, December 10, 2001, from 8:30 a.m. to 4 p.m., and from 8:30 a.m. to 12 p.m. on Tuesday, December 11, 2001. The agenda for this inaugural meeting will include overview of VA policies concerning approval of licensing and certification testing. The majority of this initial meeting will be dedicated to determining the functions of the Committee. Established by Public Law 106–419, the purpose of the Committee is to provide advice and counsel to the Secretary of Veterans Affairs on matters regarding the requirements of organizations or entities offering licensing and certification tests taken by individuals entitled to payment under VA's education and training programs and on related issues as the Committee determines is appropriate. Those planning to attend this open meeting should contact Ms. Lynn M. Cossette or Mr. William G. Susling at (202) 273–7187 by November 30, 2001.

Dated: November 15, 2001.

By Direction of the Secretary:

Nora E. Egan,

Committee Management Officer.

[FR Doc. 01–29202 Filed 11–21–01; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register

Vol. 66, No. 226

Friday, November 23, 2001

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1163–F]

RIN 0938–AK47

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities-Update; Final Rule

Correction

In the issue of Monday, September 17, 2001, on page 48078, in the correction of rule document 01–18869, in the third column, in the first full paragraph, in the fourth line, ''§415.102'' should read, ''§415.102(a)''.

[FR Doc. C1–18869 Filed 11–21–01; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 8

[Docket No. 01-23]

RIN 1557-ACOO

Assessemnt of Fees

Correction

In rule document 01–28692 beginning on page 57645 in the issue of Friday, November 16, 2001, make the following corrections:

§8.2 [Corrected]

1. On page 57647, §8.2 (a), in the table at the bottom of the page, first column, eighth figure,''16,000'' should read ''6,000''.

2. On the same page, §8.2 (a), in the table at the bottom of the page, first column, tenth figure, ''140,000'' should read ''40,000''.

[FR Doc. C1–28692 Filed 11–21–01; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,

November 23, 2001

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 410

Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS–3250–F]

RIN 0938–AL03

Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services

AGENCY: Center for Medicare & Medicaid Services, (CMS) HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B to promote Medicare program integrity and national uniformity, and simplify administrative requirements for clinical diagnostic laboratory services. This rule addresses public comments received on the proposed rule that was published March 10, 2000. A Negotiated Rulemaking Committee (the Committee) developed the policies as directed by section 4554(b)(1) of the Balanced Budget Act of 1997 (the BBA).

DATES: Effective November 25, 2002, except for sections 410.28(f), 410.32(d) redesignations, (d)(1) heading, (d)(4) and (e), which are effective February 21, 2002. See the effective date section of the preamble for a discussion of the effective dates for provisions that were discussed in the preamble but not codified in the rule.

FOR FURTHER INFORMATION CONTACT: Jackie Sheridan, (410) 786–4635 (for issues related to coverage policies). Brigid Davison, (410) 786–8794 (for issues related to documentation requirements). Dan Layne, (410) 786–3320 (for issues related to claims processing).

SUPPLEMENTARY INFORMATION: The sections contained within this document have been constructed according to the framework outlined in the table of contents that follows. We summarized pertinent material from our proposed rule that was published on March 10, 2000 (65 FR 13082) followed by public comments and our responses.

Table of Contents

I. Background

A. Current Statutory Authority and Medicare Policies

Section 1833 and 1861 of the Social Security Act (the Act) provides for payment of, among other things, clinical diagnostic laboratory services under Medicare Part B. Tests must be ordered either by a physician, as described in § 410.32(a), or by a qualified nonphysician practitioner, as described in § 410.32(a)(3). Tests may be furnished by any of the entities listed in § 410.32(d)(1). A laboratory furnishing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100–578), as set forth at 42 CFR part 493. Part 493 applies to laboratories seeking payment under the Medicare and Medicaid programs.

Section 1862(a)(1)(A) of the Act, to which there are certain explicit statutory exceptions, provides that no Medicare payment may be made for expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Moreover, section 1862(a)(7) of the Act excludes coverage ''where such expenses are for routine physical checkups, eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examination therefore, or immunizations (except as otherwise allowed under section 1861(s)(10) and paragraph (1)(B) or under paragraph (1)(F).

Under the above statutory authority, we have issued national coverage decisions and policies in a variety of documents, such as Centers for Medicare & Medicaid Services manual instructions, **Federal Register** notices, and Centers for Medicare & Medicaid Services Rulings. We have issued approximately 20 national coverage decisions pertaining to clinical diagnostic laboratory services in the Medicare Coverage Issues Manual (CMS Pub. 6). Medicare program manuals are posted on the Internet at *http://www.cms.gov/pubforms/progman.htm.* Program transmittals and program memoranda are posted at *http://www.cms.gov/pubforms/transmit/transmit.htm.*

Under section 1842(a) of the Act, we contract with organizations to perform bill processing and benefit payment functions for Medicare Part B (Supplementary Medical Insurance). These Medicare contractors, who process Part B claims from noninstitutional entities, are called carriers. Under section 1816(a) of the Act, we contract with fiscal intermediaries to perform claims processing and benefit payment functions for Medicare Part (Hospital Insurance). Fiscal intermediaries also process claims payable from the Medicare Part B trust fund that are submitted by providers that participate in Medicare Part A, such as hospitals and skilled nursing facilities. We use the term ''contractor(s)'' to mean carriers and fiscal intermediaries.

Medicare contractors review and adjudicate claims for services to ensure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. In the absence of a specific national coverage decision, coverage decisions are made at the discretion of the local contractors. Frequently, local contractors publish local medical review policies (LMRPs) to provide guidance to the public and medical community that they service.

Contractors develop these local medical review policies by considering medical literature, the advice of local medical societies and medical consultants, and public comments. Our instructions regarding the development of local medical review policies appear in section 2.3 of the Program Integrity Manual (CMS Pub. 83).

These LMRPs explain when an item or service will (or will not) be considered ''reasonable and necessary'' and thus eligible (or ineligible) for coverage under the Medicare statute. If a contractor develops an LMRP, its LMRP applies only within the area it serves. While another contractor may come to a similar decision, we do not require it to do so. An LMRP may not conflict with a national coverage decision once the national coverage decision is effective. If a national coverage decision conflicts with a previously established LMRP, the contractor must change its LMRP to conform to the national coverage decision. A contractor may, however, make an LMRP that supplements a national coverage decision where the national coverage decision is silent on an issue. The LMRP may not alter the national coverage decision.

B. Recent Legislation

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, mandates use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. Section 4554(b)(2) of the BBA requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Medicare Part B in connection with the following:

- Beneficiary information required to be submitted with each claim or order for laboratory services.
- The medical condition for which a laboratory tests is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Act).
- The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.
- The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test (in accordance with section 1833(e) of the Act).
- Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding these requirements.
- Procedures for filing claims and for providing remittances by electronic media.
- Limitations on frequency of coverage for the same services performed on the same individual.

II. Provisions of the March 10, 2000 Proposed Rule

In the March 10, 2000 proposed rule, we set forth uniform national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. These proposed policies were designed to promote Medicare program integrity and national uniformity and simplify administrative requirements for clinical diagnostic laboratory services. These regulations do not provide, or purport to provide, any immunities or safe harbors. Additionally, these regulations do not limit any criminal, civil, or administrative law enforcement and overpayment actions. These Medicare policies apply to all Medicare contractors processing Part B laboratory claims, including fiscal intermediaries.

The preamble to the March 10, 2000 proposed rule discussed the composition of the Committee, the guidelines the Committee followed in making recommendations, and the consensus of the negotiating Committee. Most of the provisions of the rule will be implemented through our instructional issuance system rather than codified in regulations, but were discussed in the preamble to the March 10, 2000 proposed rule nonetheless. A summary of the preamble of the March 10, 2000 proposed rule is as follows:

- Information required with each claim.

—Claims processing requirements change regularly; therefore, we encourage readers to refer to the claims processing sections of the Medicare Carriers Manual (sections 3005 and 3999, exhibit 10) and Medicare Fiscal Intermediary Manual (section 3605 and Addendum L) in order to keep current regarding the specific policies related to data elements. These manuals are posted on the Internet at *http://www.cms.gov/pubforms/progman.htm.*

—We proposed not to require that diagnostic information be submitted with every claim at this time. However, we encourage physicians to voluntarily provide diagnosis information (either the reason for the visit or the reason for the test) with the order, and we encourage laboratories to submit information that they receive with the claim.

—In order to promote uniformity, we proposed that the date of service for laboratory tests that is reported on the claim be the date the tested specimen was collected. The person obtaining the specimen must furnish the date of collection of the specimen to the entity billing Medicare.

- Medical conditions for which a test may be reasonable and necessary.

—The March 10, 2000 proposed rule discussed the uniform process that the Committee used in developing 23 national coverage decisions. We are not codifying the national coverage decisions (NCDs) so that they could be updated in a timely manner as appropriate to accommodate changes in technology, coding, or national practice standards. We used the following process to develop the NCDs:

++ Seeking input from relevant national medical specialty societies and voluntary health agencies through the American Medical Association representative.

++ Reviewing relevant scientific literature and practice guidelines.

++ Reviewing existing local medical review policies, as well as any existing relevant templates for local policies developed by a task force of carrier medical directors.

++ Soliciting comments on the draft policies through an Internet posting from November 4 through 11, 1998.

—The policies followed a uniform format that Included a narrative description of the test, panel of tests, or group of tests addressed in the NCD; clinical indications for which the test(s) may be considered reasonable and necessary and not screening for Medicare purposes; limitations on use of the test(s); and diagnosis codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM codes); reasons for denial (the content of which was not negotiated by the Committee); sources of information on which the decision is based; and coding guidelines.

The ICD–9–CM codes were displayed in one of three sections. The first section lists covered codes—those for which there is a presumption of medical necessity but the claim may be subject to review. The second section lists diagnosis codes that are never covered. The third section lists codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Additional documentation could support a decision of medical necessity and must be submitted by the ordering provider and accompany the claim.

The national coverage decisions apply nationwide and are binding on all Medicare carriers, fiscal intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans for purposes of Medicare coverage. In accordance with section 522 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Beneficiaries who file for review of NCDs on or after October 1, 2001 may appeal to the Department of Health and Human Services Appeals Board for review.

—The policies may be updated and new laboratory policies developed under the Medicare national coverage process that was published April 27, 1999 (see 64 FR 22619). A copy of this general notice is posted on the Centers for Medicare & Medicaid Services Internet site at *http://www.cms.gov/coverage/8a1.htm*

- Appropriate use of procedure codes.

—We clarified that the term screening or screen in Current Procedure Terminology (CPT) Codes does not necessarily describe a test performed in the absence of signs or symptoms of an illness, disease, or condition.
—We clarified use of the −59 modifier as an indication for claims for multiple billings of the same CPT code for the same beneficiary for the same day when those services are medically necessary.

• Documentation and recordkeeping requirements.

—We proposed adding language to the Code of Federal Regulations (CFR) to clarify the documentation physicians and laboratories, respectively, are required to maintain.
—We proposed CFR provisions clarifying that if the documentation submitted by the entity submitting the claim is inadequate, we will seek information directly from the ordering physician.
—We clarified that we do not require the signature of the ordering physician on a requisition for laboratory tests. However, documentation that the physician ordered the test must be available upon our request.
—We summarized the various record retention requirements that presently exist.

• Procedures for filing claims.

—We clarified that the entity submitting the claim may assign an appropriate diagnosis code to a narrative, even if there is not an exact match between the code descriptor and the narrative the laboratory received from the ordering physician.
—We clarified that until standards permitting eight ICD–9–CM codes are implemented, Medicare contractors, whose systems accept fewer than eight ICD–9–CM codes in the diagnoses field, would permit the laboratory to submit additional codes in the narrative field.
—We encourage matching of procedures to diagnoses, but we clarified that claims would not be denied solely because there is no matching of diagnosis and procedure codes on the claim form. In lieu of identifying a noncovered service through matching noncovered diagnoses to specific procedures on a claim, we also proposed that laboratories have the option of submitting a separate claim for a procedure that is not covered by Medicare.

• Limitation on frequency.

—We proposed to issue instructions that state February 21, 2002 that contractors may not use a frequency screen that could result in a frequency-based denial unless information published by us or our contractors includes an indication of the frequency that is generally considered reasonable utilization of that test for Medicare purposes.
—We proposed to clarify the CFR provision by including the existing requirements related to automatic denials from the manual in the CFR.
—We solicited new ideas for addressing the problem of notification of beneficiaries of potential overutilization of testing.
—We proposed to issue instructions February 21, 2002 that all Medicare contractors consistently use remittance advice language that identifies the reason for denial as excess frequency when that is the reason for denial.

• We clarified that the limitation on liability provisions that are currently found in section 1879 of the Act, 42 CFR part 411, subpart K, section 7330 of the Medicare Carriers Manual, section 3440 through 3446.9 of the Fiscal Intermediary Manual, and any currently applicable rules are equally applicable to laboratory services.

The changes we proposed to make to § 410.32 are set forth as follows:

• We proposed to redesignate paragraph (d) introductory text as paragraph (d)(1), and we proposed to add a heading.

• We proposed to redesignate paragraphs (d)(1) through (d)(7) as paragraphs (d)(1)(i) through (d)(1)(vii).

• We proposed to add a new paragraph (d)(2) to § 410.32 that would outline documentation and recordkeeping requirements related to clinical diagnostic laboratory tests. The documentation and recordkeeping requirements read as follows:

++ Paragraph (d)(2)(i) would specify that the physician (or qualified nonphysician practitioner) who orders the service must maintain documentation of medical necessity for the service in the beneficiary's medical record.

++ Paragraph (d)(2)(ii) would require the entity submitting the claim to maintain documentation it receives from the ordering physician and information documenting that the claim submitted accurately reflects the information it received from the ordering physician.

++ Paragraph (d)(2)(iii) would authorize the entity submitting the claim to request additional diagnostic and other medical information from the ordering physician to document that the services it bills are reasonable and necessary. This request must be relevant to the medical necessity of the specific test(s), and take into consideration current applicable rules and regulations on patient confidentiality.

• We proposed adding a new paragraph (d)(3) to § 410.32 relating to claims review.

++ Paragraph (d)(3)(i) will specify that the entity submitting the claim must provide documentation of the physician's order for the service billed, showing accurate processing and submission of the claim, and diagnostic or other medical information supplied to the laboratory by the ordering physician or qualified nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

++ Paragraph (d)(3)(ii) will specify that if the documentation submitted by the laboratory does not demonstrate that the service is reasonable and necessary, we will provide the ordering physician information sufficient to identify the claim being reviewed and request from the ordering physician those parts of the beneficiary's medical record that are relevant to the claim(s) being reviewed. If the documentation is not provided timely, we will notify the billing entity and deny the claim.

++ Paragraph (d)(3)(iii) will authorize the entity submitting the claim to request additional diagnostic and other medical information that is relevant to the medical necessity of the specific services from the ordering physician consistent with applicable patient confidentiality laws and regulations. h We proposed adding a new paragraph (d)(4) to § 410.32 to outline when we may deny a claim without manual review.

++ Paragraph (d)(4)(i) will state that unless indicated in paragraph (d)(4)(ii), we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim.

++ Paragraph (d)(4)(ii) will permit automatic denial of claims when there is a national coverage decision, or LMRP that specifies the circumstances under which the service is denied, or the statute excludes Medicare coverage for the service, or the specific provider or supplier has engaged in egregious overutilization of the service and the claim is for that service.

III. Comments and Responses Based on the March 10, 2000 Proposed Rule

We received responses from 61 commenters during the public comment period. The commenters included many of the members of the negotiation

committee; other national and State organizations, such as the American Society of Hematology, and the Iowa Association of Pathologists; representatives of various laboratories and hospitals; individual physicians and other health care practitioners; a seniors' legal advocate; and a Medicare contractor medical director.

Information Required With Each Claim

Comment: Eighteen commenters expressed concern that the proposed rule did not specifically require physicians to provide information necessary to support medical necessity. The commenters believe that laboratories billing Medicare will have to collect information from various sources to support medical necessity. The commenters proposed that the final rule should clearly state that physicians are required to provide the information necessary to support medical necessity with the order, if that information is needed for claims processing.

Response: The Committee discussed when diagnostic information to support medical necessity must be submitted with a claim. The Committee's discussion focused on whether diagnostic information should be required on claims for all tests, even those not addressed by a national coverage policy or LMRP. Some Committee members emphasized that providing information related to the reason for the patient visit or for the test would be useful in evaluating patient outcomes and quality of care and would ensure consistency and simplicity. Physicians' representatives expressed concern, however, about the burden that may be involved in providing the information. Laboratory representatives expressed concern about laboratories' ability to be paid if the physician does not provide the information.

The Committee concurred that this proposed rule would not promulgate a requirement that diagnostic information be submitted with every claim. While we recognize the concerns of the commenters, we believe that such a requirement would present significant burdens on some physicians. We will continue to study this issue and weigh the benefits of requiring diagnostic information on every claim for laboratory services against the burden that it would impose on physicians and laboratories. We welcome the public to share with us any specific suggestions they have for mitigating the burden on physicians inherent with instituting a mandatory diagnostic information requirement.

In addition, we encourage physicians voluntarily to provide diagnostic information (either the reason for the visit or the reason for the test) with the order. Likewise, we encourage laboratories to submit information that they receive with the claim. Of course, if the diagnostic information is required for claims payment, such as where there is published national or local policy, physicians and practitioners are required under section 4317(b) of the BBA to provide diagnostic information at the time that the test is ordered.

Comment: One commenter expressed concern about the proper procedure with which to handle patients who have no referring diagnosis but can provide complaint, symptoms, or diagnosis. The commenter believes that not having a process to handle those situations may result in the patient experiencing delay or postponement of the service.

Response: For situations in which the patient does not present with a referring diagnosis but is able to provide complaint, symptom(s), or diagnosis, the proposed rule stated that the patient should be coded to the highest level of specificity that corresponds to his/her state of health. That is, the physician should provide this information (in narrative or code) to the laboratory, and the laboratory should report the complaint or symptom as one of the diagnoses on the claim. The national coverage decisions in this final rule include appropriate ICD–9–CM codes for relevant signs and symptoms in the sections entitled ''ICD–9–CM Codes Covered by Medicare Program.''

Comment: Twenty-eight commenters addressed the issue of date of service, which is defined in the proposed rule as the date of specimen collection. Twenty-one of the commenters generally agreed with the proposed rule's definition, but made suggestions for additional information or clarifications, such as the following in the definition: include the time the specimen was collected; clarify how to handle archived specimens and collections that span a 24-hour time period; specify that the entity collecting the specimen be responsible for reporting the date of service; and ensure that the laboratory is not held liable if an inaccurate date was reported on Medicare claims.

One commenter suggested that laboratories should be given the flexibility to also define date of service as the date of accession in cases for which date of collection is not available.

Six commenters were not in favor of the proposed definition on date of service and submitted suggestions about how the date of collection may be redefined. Three commenters suggested that the definition be changed to the date of accession. Two commenters suggested that the definition be changed to the date the test results were reported. In addition, one commenter suggested that laboratories be given the flexibility to choose the date of service as either the date of collection, date test results were reported or the date of accession in the laboratory. One commenter suggested that we reserve the dates of service issue for further study and not proceed with finalization of the proposal in this rule.

Response: The date of service is a required data field for laboratory claims. A laboratory service may take place over a period of time. That is, the date the physician orders the test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date of the test, and the date results are produced may not be the same. For example, often several days elapse between taking a sample and producing results in microbiology tests that are cultured. The Committee discussed what ''date of service'' laboratories must report on claims for clinical diagnostic laboratory services. To ensure equitable treatment of beneficiaries and providers, as well as to promote national claims processing consistency, it is necessary that all laboratories report this date consistently.

We are committed to establishing a national coverage policy regarding the date of service for Medicare claims that will promote program integrity and national uniformity, yet minimize the burden on laboratories. Laboratory representatives reported that some laboratory computer systems are programmed to report the date of acquisition of the specimen or the date of accession (the date the test is entered into the computer system), in the date of service field on the claim form. In addition, Medicare issued Program Memorandum A–95–4 in April 1995 that instructed hospital-based laboratories to report the date of performance as the date of service for automated multi-channel tests.

We believe that the date of collection most closely relates to the date the test was ordered and that the use of only one date of service is consistent with the goal of promoting program integrity and national uniformity. We also agree that in order to promote national uniformity, the claims processing instruction implementing this provision needs to include clarifications regarding handling of special circumstances, such as archived specimens and tests requiring extended acquisition time.

For specimen collections that span more than a 24-hour period, the

implementing instructions will clarify that the entity performing the collection should define the date of service as the date the collection began. For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.

One commenter suggested that the time of specimen collection also be reported. We do not see the need for this information in processing Medicare claims. Further, the computer software used by the industry and us for claims processing does not include a field to report this information. Thus, the addition of specimen collection time as a required element on Medicare laboratory claims would result in a substantial cost for all involved parties. The commenter did not identify benefits from this addition that were commensurate with the costs. Consequently, we are not adopting this change.

Several of the laboratory representatives commenting on this issue expressed concerns with the potential problems that may arise when the entity collecting the specimen fails to comply with the requirement to supply the specimen collection date. The implementing instruction for this provision will carefully emphasize the requirement to those collecting specimens to report the date of collection. We are optimistic that after adequate education from us and the Committee member organizations, such as the American Medical Society and national laboratory organizations, most of those collecting specimens for laboratory testing will take care to report required information. We do not believe that it is consistent with the statutory requirement to promote national uniformity to permit a variety of means to report the date of service.

We note, however, that we are providing a grace period of up to 12 months after the effective date of the final rule to accommodate any system changes required by the policy changes or clarifications resulting from the provisions of this rule. Entities that want to obtain the benefit of a grace period to permit additional time to implement computerized system changes must contact us in writing 90 days before the effective date of the provision(s) they are not able to implement timely.

The request for a grace period must include a description of the nature of the system change not able to be implemented timely, a description of the actions the entity has taken in an effort to implement timely, date upon that the entity will be able to implement fully, and a workplan with a timeline providing a detailed description of the acts which the entity shall undertake to accomplish full implementation and the dates by which acts shall be performed. We will review the submittal and advise the entity if we grant or deny the request for a grace period. We may grant or deny the request for a grace period at our discretion. Notwithstanding the foregoing, we may terminate at any time any grace period already provided if we determine that the entity has not acted in good faith or we determine the entity has failed to perform any of the conditions upon which we agreed to extend a grace period.

If we need additional time to implement system changes associated with a particular provision of this rule on a nationwide basis, we well issue a program memorandum detailing the rationale for the extension and provide a new effective date.

Thus, laboratories will have up to 24 months (12 months delayed effective date and up to 12 months grace period for system changes) after publication of the final rule to achieve system modification to submit claims in accordance with the final policy on date of service. We believe this extended time before implementation will ease any anticipated problems with the reporting of the specimen collection date.

Medical Conditions for Which a Test May Be Reasonable and Necessary

Comment: One commenter expressed concern about designating the coverage policies included in the addendum to the proposed rule as national coverage determinations. The commenter requested that national coverage determination status not be conferred to the 23 coverage policies because this would render them unchallengeable.

Response: Section 4554 of the BBA specifies that the negotiated rulemaking develop national coverage policies for clinical diagnostic laboratory services. The statute goes on to state that the rules consider the medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Act).

Our regulations do not use the term ''national coverage policies'' in developing policies that describe the medical conditions for which a test is reasonable and necessary. Rather, § 405.860 defines national coverage decisions (NCDs) in this fashion. Specifically, the section of the regulation states, ''CMS makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure, or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.'' We believe that the Congress by requiring the Secretary to adopt ''national coverage and administrative policies for clinical diagnostic laboratory tests under part B of title XVIII,'' clearly intended the coverage policies developed under this rule to be considered as NCDs. We believe that to not confer NCD status on these policies would conflict with the statutory intent of section 4554(b) of the BBA.

We note, however, that the policies are developed to provide flexibility in all but a very limited number of diagnoses. That is, the policies have been constructed in a fashion to permit a Medicare contractor to consider coverage of additional indications on a case-by-case basis.

The Committee consensus includes the restatement of existing Medicare program requirements that contractors consider all information that is submitted with a claim. The policies include very few diagnoses that may not be covered under any circumstances in the section entitled ''ICD–9–CM Codes Denied.'' Codes included in the list entitled ''Codes That Do Not Support Medical Necessity'' may be covered when they are accompanied by sufficient medical justification for the test for a particular patient's condition.

Thus, the commenter's concern that NCD status would establish an irrefutable barrier to coverage is not inherent in the NCDs as negotiated. Moreover, section 522 of BIPA includes a provision to provide for review of NCDs with regard to requests for review of NCDs filed on or after October 1, 2001. Under the provisions of section 522 of BIPA, a beneficiary who is adversely affected by an NCD may request a review with the Department of Health and Human Services Appeals Board (DAB). The DAB may take evidence, consult with appropriate scientific and clinical experts and will look at the reasonableness of the determination. Final decisions of the DAB are subject to judicial review. Thus, the policies will be reviewable.

Comment: One commenter expressed concern that the March 10, 2000 proposed rule did not specifically state that a laboratory is not required to provide an advance beneficiary notice with respect to the ICD–9–CM codes that are listed in the category ''ICD–9–CM Codes Denied.''

Response: The diagnoses listed in the section entitled ''ICD–9–CM Codes Denied'' are codes that are not covered by Medicare for a variety of reasons. For example, some codes are excluded because they are screening services;

others are listed because they are services to caretakers rather than beneficiaries; another is based on the hearing aid exclusion. Advance Beneficiary Notices (ABNs), with respect to laboratory services, are required only for claims that the provider or supplier believes may not be covered by Medicare based on section 1862(a)(1) of the Act (reasonable and necessary exclusion).

Historically, Medicare's exclusion of screening services has been attributed to section 1862(a)(7) of the Act. In a 1988 Program Memorandum (AB–88–2), we stated that we consider the 1862(a)(7) of the Act exclusion to be the basis for denial of screening services. Thus, under current policy, providers or suppliers are not required to provide the beneficiary with an ABN before to billing them for screening tests that are provided for the diagnoses listed in the section entitled ''ICD–9–CM Codes Denied.'' However, we believe that advance notice to beneficiaries of that liability is prudent, and we encourage providers and suppliers to voluntarily notify beneficiaries that they will be liable for the cost of the tests.

We are, however, reconsidering whether to exclude screening tests based on section 1862(a)(7) of the Act rather than section 1862(a)(1)(A) of the Act. We are concerned that it may not be in the best interest of our beneficiaries to permit providers and suppliers to bill them for screening services without advance notice. Should we issue a change to the policy, laboratories will be required to issue ABNs for services that are not covered based on the diagnoses in the list that are screening services. Any such change would be prospectively effective.

Comment: Two commenters addressed the fact that the 23 tests identified in the national coverage decision represented 60 percent of the volume of Medicare outpatient laboratory testing. The commenters requested information about what percentage of Medicare outpatient laboratory payments is represented by the 23 laboratory services.

Response: We performed an analysis on the 1999 bills that were processed by the Medicare carriers. This database does not include the laboratory claims processed by hospital-based laboratories. In this data set, the 63 laboratory tests that make up the 23 services represent 43 percent of carrier lab services and 51 percent of carrier laboratory payments.

Comment: Two commenters expressed concern with the development of policies using both an inclusionary and exclusionary basis. They noted that using two different forms of logic in the development of computer edits is costly. They suggested that we re-evaluate the benefits of this approach relative to the benefits.

Response: We decided to display the diagnosis codes in the coverage policy for blood tests on an exclusionary basis. That is, rather that list the ICD–9–CM diagnosis codes than presumptively support medical necessity of a blood count, they listed the codes for which a blood count would not be presumptively medically necessary. We decided to use the exclusionary approach for listing the codes when the list of codes that supported medical necessity was considerably larger than the list of those that did not. Thus, blood counts was the only test that was developed using the exclusionary approach.

We note that the coverage policy for blood counts was developed in the same manner as all other tests. That is, based on scientific evidence, we listed those conditions that are indications for the test, or the inclusionary approach. It was for reasons of administrative simplicity that we displayed the codes in an exclusionary manner. Thus, any organization developing its own internal edits is free to edit using an inclusionary approach of computer logic by listing the codes that are not displayed as excluded.

Comment: One commenter suggested that the narrative indications and the ICD–9–CM codes contained in the policies needed to be reviewed for consistency in all sections. The commenter believes that not all codes that can be used for the indications have been included in the list for ''ICD–9–CM Codes Covered by Medicare Program.'' However, the commenter did not make specific suggestions for changes.

Response: During the development of the proposed policies, we made a valiant effort to ensure that the coding corresponded to the indications included in the NCDs. This effort included development of the initial list of codes by an interdisciplinary workgroup that included at least one ICD–9–CM coding expert designated by the American Health Information Management Association, as well as multiple physicians, including Medicare contractor medical directors who are familiar with coding from their claims analysis activities. After the workgroup produced the draft NCDs, they were posted on the Internet for public comments.

Several of the public comments related to coding suggestions, which the Committee took under advisement in making its final recommendations. We assigned a team of coders and physicians to review the recommended policies as well before they were published as proposed policies in the **Federal Register**.

In addition, to help ensure a complete listing of codes, we specifically solicited comments on the policies from the public in the preamble to the proposed rule. However, in that preamble we explicitly stated that requests for changes should be accompanied by scientific evidence supporting the request. We encouraged commenters ''to submit, with their comments, copies of medical literature supporting their recommendation for change * * *''

We received a number of comments regarding specific codes that members of the public believe were appropriate changes to the lists. None of the requests or comments regarding coding changes was accompanied by supporting scientific evidence, however. As discussed more fully in subsequent comments, we carefully reviewed each of these suggestions using a team of our physicians and coding experts and made appropriate decisions regarding their inclusion in the list based on the indications described in the policies.

We believe the use of the Committee to develop the initial list of covered codes, together with the opportunity for public comment both during the Committee meetings and in response to the March 10, 2000 proposed rule provides adequate assurances that the list of codes is appropriate. If members of the public have additional suggestions, we invite them to use the national coverage process to request specific changes for the future.

Comment: One commenter expressed concern with the language in the ''Reasons for Denial'' section relating to Food and Drug Administration (FDA) approval or clearance of tests. The commenter believes that there are additional exceptions beyond the Category B Investigation Device Exemption (IDE) noted in the March 10, 2000 proposed rule. The commenter suggested that the language provide for other exceptions. Further, the commenter requested that we specify the procedures that would apply to this section through an additional document that would be subject to notice and comment.

Response: The last bullet in the Reasons for Denial section of the proposed policies states that ''Tests that require FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of

Category B IDE devices is left to contractor discretion. (See 60 FR 48425, September 19, 1995).'' The purpose of including the reasons for denial was to provide information that may be helpful to users of the policy. We note that this section was not negotiated by the Committee and included general policies of Medicare that apply to various types of services rather than being specific to laboratory services.

Subsequent to the publication of the March 10, 2000 proposed rule we published a policy on Medicare coverage of services under clinical trials. This policy was published on our coverage web site on the Internet (http://www.cms.gov/coverage/8d.htm) and in Program Memorandum AB–00–89 and Coverage Issues Manual Section 30–1. The national coverage decision that related to clinical trials provides for coverage of routine costs incurred during certain clinical trials. Thus, as the commenter noted, there are other exceptions to FDA approval. As part of implementation of this policy, we will be modifying our regulations governing coverage of IDEs that was referenced in this bullet. We believe it is appropriate to remove this bullet from the reasons for denial section at this time. We should point out, however, that we will continue to consider FDA approval when appropriate in making coverage determinations on Medicare claims.

Comment: One commenter noted that none of the coverage policies considered family history as a medically necessary reason for a test. The commenter believes that in a limited number of diseases family history should be included as a basis for diagnostic testing, but did not identify any specific conditions.

Response: The policies have been developed based on Medicare's long-standing interpretation of sections 1862(a)(1)(A) and 1862(a)(7) of the Act. Section 1862(a)(1)(A) of the Act provides that Medicare payment may only be made for services that are reasonable and necessary for the diagnosis or treatment of illness or injury. Section 1862(a)(7) of the Act excludes Medicare coverage of routine physical checkups. We have interpreted this to exclude routine testing provided during such a physical checkup. Thus, all of the policies were developed based on the concept that tests that are performed when no specific sign, symptom, or diagnosis is present and when the patient has not been exposed to a disease are excluded from coverage as screening services. (See Coding Guideline #2.)

We, as well as many members of the Committee, recognize that there may be many instances when testing of beneficiaries in the absence of specific signs, symptoms, diagnosis, or exposure to disease is good health care. The value of many preventive services and screening tests, particularly in the case of family history of disease is well documented. The exclusion of family history was not based on a belief by the Committee or us that such testing should not be performed.

We are considering generating an internal request for a national coverage decision addressing the role of family history as a medical justification for a test being reasonable and necessary under our national coverage decision process. National coverage decisions are evidence-based decisions. If, after careful analysis, we believe there is a basis for covering screening services, we will post a notice on our coverage page on the Internet to allow the public an opportunity to participate by submitting evidence for our further consideration.

Comment: One commenter expressed concern that certain pre-operative tests were not included in the proposed policies. The commenter explained that surgeons and other involved physicians will be bound by unreasonable and inflexible protocols that impose barriers to prudent management of an individual patient about to undergo surgery.

Response: The coverage policies negotiated by the Committee are evidence-based policies. In situations in which the scientific evidence supports the administration of tests, such as blood counts, prothrombin time and partial thromboplastin time, before surgery, the policies provide for coverage of these tests.

There are a number of other tests, however, that are routinely administered to all patients about to undergo surgery in some hospitals. We note that the value of that routine testing for all patients undergoing all surgery is questionable. For example, a recent study of pre-operative testing of cataract patients showed that the routine testing did not affect the outcome of the patients. (*The New England Journal of Medicine* 342 (2000): 168). Based on our discussion with physicians on this issue, we have concluded that there is not consensus among physicians regarding the appropriateness of furnishing a broad spectrum of tests to seemingly well individuals merely because they are about to undergo surgery.

We believe that the proposed policies developed by the Committee appropriately handle the issue of pre-operative surgery given the constraints of the law related to screening that are discussed above. That is, tests furnished to patients who present with signs, symptoms, or history of disease are covered for those conditions. Although screening individuals without signs, symptoms, or past history may be good medical practice, we do not believe it is a service that is covered by the Medicare program.

However, we are interested in continuing to study this issue. We encourage the public to use the national coverage process discussed elsewhere in this document to forward to us any scientific literature related to improvements in outcomes associated with administering specific pre-operative laboratory tests routinely to Medicare patients.

Comment: One commenter expressed concern that the proposed policies may not be appropriate for certain populations. The commenter was particularly concerned that the proposed policies did not address the specific needs of certain socioeconomic or ethnic groups.

Response: We acknowledge that the proposed policy does not generally address specific socioeconomic or ethnic groups. Generally, additional testing of particular socioeconomic or ethnic groups is based on higher propensity for a disease state, which is considered screening. Rather, the policies were designed to identify the specific medical indications (signs, symptoms, or disease) for testing that were supported by the scientific literature. However, the policies were not designed to be an irrefutable list of diagnoses that may warrant a particular test. Diagnoses, other than those listed in the section entitled ''ICD–9–CM Codes Denied,'' or more frequent tests may be covered on an individual basis when they are supported by medical justification submitted with the claim.

Comment: One commenter suggested that the title of the list of codes called ''ICD–9–CM Codes Denied'' be changed to ''ICD–9–CM Codes Denied as Not a Benefit of Medicare'' to clarify that these are not medical necessity denials.

Response: As noted above, we are re-evaluating our policy related to screening services. Thus, we do not believe it is in the best interest of the users of the policy to change the title of this section at this time.

Comment: One commenter requested that the coding guidelines remain in the Coding Clinic of the American Hospital Association (AHA), rather than in the **Federal Register**. The commenter explained that AHA's Coding Clinic for ICD–9–CM is a more flexible means of updating codes than is the **Federal Register**, in which changes would be

subject to administrative processes such as notice and comment periods.

Response: Several of the coding guidelines from the AHA Coding Clinic were printed in the proposed coverage policies for purposes of providing assistance to the users of the policies. We believe that repeating certain coding guidelines in the policies would clarify coding policies for users and would be beneficial because users would not need to consult alternative manuals for expeditious resolution of common coding questions.

The incorporation of existing coding guidelines in the national coverage determinations was not intended to imply that future changes to the coding guidelines would be subject to publication in the **Federal Register** or make composite coding guidelines subject to the Administrative Procedure Act. If one of the coding guidelines that was printed in the proposed policies is changed in the future, the revised guideline may be incorporated into a national coverage decision through the NCD coverage process without publication in the **Federal Register**.

Comment: One commenter expressed concern with coding guideline 2 on screening services. The commenter believes that the V01 codes, contact with or exposure to communicable diseases should be denied under all circumstances as screening. Further, the commenter suggested clarification of coding when a screening test shows an abnormal finding.

Response: We believe that confirmed exposure to disease is not considered a screening test in all circumstances. For example, the proposed policy does not consider HIV testing of patients who have been exposed to HIV through needlesticks from an HIV-positive patient as screening. Further, Medicare Program Memorandum AB–99–04 details that we do not consider testing for hepatitis C infection screening when it is performed on patients who have been exposed to hepatitis C through a blood transfusion from a patient that later is determined to have hepatitis C. Thus, we are not adopting the commenter's first recommendation.

We acknowledge that the appropriate coding for tests that were ordered as screening, but show abnormal findings, is an issue that needs clarification. We have learned that there are significant differences in the common coding practices between hospitals and nonhospital settings. We believe, however, that this issue is most appropriately handled by the ICD–9–CM Coding Committee. The ICD–9–CM Coding Committee is comprised of representatives from Centers for Medicare & Medicaid Services, the AHA and the National Center for Health Statistics, who are experts in the coding field. They are best able to discuss the differences among the various uses of coding guidelines and issue clarifications. We will ask the ICD–9–CM Coding Committee to include this issue on an upcoming agenda. Clarification will be published through the AHA Coding Clinic when the differences are resolved.

Comment: One commenter made reference to coding guideline #5, which refers to nonspecific codes. The commenter believes the guideline does not define nonspecific codes, nor is the appropriate meaning of the term clear. The commenter requested that the final rule clarify whether the term ''non-specific codes'' refers to the ICD–9–CM code ''not otherwise specified'' (codes ending in an 8) or ''unspecified'' (codes ending in 9) or something else.

Response: Coding guideline #5 states, ''When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indication for the test above.'' In including this statement in the coding guideline, the Committee was not addressing the ''not otherwise specified'' or ''unspecified'' codes exclusively. Rather, the list of covered codes frequently includes codes that are very broad and encompass several related but different conditions, only a few of which would justify the test in question.

For example, assume that a given code (X) is appropriate for three conditions (A, B, and C). An indication for test 1 is condition A. The coding guideline is intended to remind users that if you report code X for test 1, it is expected that the patient have condition A. In other words, if upon medical review of the chart, the contractor finds that the patient only has condition B, which is not included in the indications, it may deny the claim despite the fact that code X is included in the list of codes that support medical necessity.

Comment: Many commenters suggested additional

ICD–9–CM diagnosis codes be added to the various policies. The commenters generally did not provide rationale for the suggestions and none of the requests were supported with scientific evidence as we specifically requested in the preamble of the March 10, 2000 proposed rule. In short, the commenters asserted the policies were incorrect or incomplete without providing explanation or support for their concern.

Response: As described in the preamble to the March 10, 2000 proposed rule and in response to another comment above, the Committee developed the policies in a systematic and uniform manner. The Committee developed the narrative portion of the NCDs based on scientific evidence. That is, the narrative indications for a test were evidence based. Once the narrative indications were developed, the Committee attempted to identify the ICD–9–CM codes that appropriately translated the narrative.

The Committee provided a brief public comment period on the policies as developed by the workgroups before the full Committee discussion of the issue and before the rule was published by Centers for Medicare & Medicaid Services on March 10, 2000. During this public comment period, numerous suggestions for coding changes, similar to those received during this public comment period, were made. In considering these public comments, the Committee decided that unless the coding changes were supported by medical evidence, the Committee would continue to look to the narrative indications and make a determination if the suggested code was an appropriate translation of the narrative.

It is critical that the narrative indications for the proposed policy and the ICD–9–CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD–9–CM codes that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative. The preamble to the March 10, 2000 proposed rule in soliciting public comments on the policies clearly requested that any suggested changes be accompanied by scientific literature supporting the change. Since both the Medicare NCD process and the negotiating committee use evidence-based decision making, it would not be appropriate to use opinion-based decision making to change the proposed policies in responding to the public comments. Therefore, we believe the approach similar to that taken by the negotiating committee in handling the comments it received from the public is a reasonable and appropriate means of addressing the suggestion for coding changes that were submitted to us during the public comment period on the March 10, 2000 proposed rule.

Since none of the suggested coding changes we received on the proposed coverage policies was accompanied by scientific literature, we looked to the

proposed narrative indications in determining if the code was an appropriate addition to the ICD–9–CM list in the policy. We used a team of our physicians and coding experts to evaluate each of the codes that was suggested during the public comment period. The team carefully studied the narrative descriptions of the indications for the test in the proposed NCDs. When the suggested code was a reasonable application of the existing narrative, we added the code to the list.

Our physicians acknowledged that many of the ICD–9–CM codes that were suggested might be clinically understandable in certain situations. However, gathering the scientific-evidence and conducting the analysis necessary to make a reasonable determination as to the appropriateness of adding indications to the proposed policies for each of the multitude of codes suggested would be a daunting task and would have resulted in unreasonable delay in the finalization of the policies. We do not believe it is appropriate to further delay adoption of the proposed policies to conduct this search for medical evidence to support unsubstantiated suggestions. However, requestors are free to use the national coverage decision process (published in the April 27, 1999 **Federal Register** (64 FR 22619) and on the Internet at *http://www.cms.gov/coverage/8a1.htm*) to request further refinement of the national coverage decisions.

The following codes were suggested for addition to specific policies. We believe these codes are an appropriate translation of the indications listed in the policy and we are adding them to the ICD–9–CM codes covered by Medicare.

Blood glucose: 780.31, 781.0, 783.6
Digoxin: 429.2, 972.0
Fecal Occult Blood Test: 003.0, 003.1, 095.2, 095.3, 098.0, 098.7, 098.84, 139.8, 159.0–159.9, 569.82, 569.83, 596.1, 751.1
Gamma Glutamyl Transferase: 230.7, 230.9, 642.5, 782.4, 789.1, 790.4, 790.5, V42.7
Lipids: 278.00, 401.0–401.9, 402.00–402.91, 403.00–403.91, 404.00–404.93, 405.01–405.99, V42.7
Prostate Specific Antigen: 236.5, 599.6, 788.30, 788.41, 788.43, 788.62
Human immunodeficiency virus testing (Diagnosis): 263.0, 263.1, 263.9, 486
Partial thromboplastin time: 362.30, 362.31, 362.32, 362.33, 362.34, 362.35, 362.36, 362.37, 410.0–.9, 456.8, 530.82,
Prothrombin time: 786.50, V12.51–V12.59
Iron studies: 579.8, 579.9, 713.0, 716.4–716.9, V56.0, V56.8
Thyroid: 290.3, 297.1, 333.99, 358.1, 359.5, 376.21, 376.22, 425.7

The following codes were suggested for changes to the NCDs.

Our physician staff and coding experts reviewed these codes. Based on their clinical judgment and knowledge of coding guidelines, we do not believe these codes appropriately stem from the indications included in the respective policies.

Blood counts: 300.00, 300.01, 575.6, V45.89, 715.00–715.98, 716.00, 716.99
Blood glucose: 279.9, 357.2, 357.8, 785.1, 800.00–804.99, 805.00–806.79, 850.00–854.19, V22.0–V22.2, V72.73–V72.84, V72.81
Iron studies: 253.5, 276.0, 276.1, 278, 282.0, 282.1, 282.2, 282.3, 282.4, 282.5, 282.60–282.63, 282.69, 282.7, 282.8, 282.9, 283.0–283.9, 289.0–289.9, 333.99, 564.5, 607.84, 708.8, 714.0–714.9, 715.0–715.9, 716.0–716.3, 733, 758.0, 758.1–758.9, 775.3, 780.4, 790.4
Partial thromboplastin time: 036, 040, 041, 050, 054, 056, 078.5, 081, 082, 083, 084, 085, 086, 087, 115, 117.3, 152.0–152.9, 162, 171, 174, 183, 185, 188.0–188.9, 198.1, 204, 205, 206, 207, 208, 239.4, 239.5, 250.1, 282, 283, 285.0, 287.3, 289.5, 290.40–290.43, 331.81, 345.3, 369.1–369.9, 377.53. 377.62, 386.2, 386.5, 394.0–394.9, 395.0, 395.2, 396.0–396.9, 397.0–397.9, 398.0, 398.90–398.99, 411.1, 411.81, 411.89, 413.0, 413.1, 413.9, 414.00–414.05, 414.8, 414.9, 415.0, 415.11, 415.99, 416.9, 424.0, 424.1, 424.90, 424.2, 424.3, 424.91, 425.0–425.9, 427.0–427.9, 436, 437, 440.0–440.9, 443.0–443.9, 447.6, 452, 459.2, 514, 555.0–555.9, 577.0, 671.9, 710, 746.00, 746.01–746.09, 746.1–746.89, 747.1, 786.50, 789.1, 789.5, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 958.1, 958.4, 991.6, 992.0, 994.1, 995.0, 996.85, V12.51, V15.1, V42.2, V42.7, V43.2, V43.4, V43.60–V43.69
Prothrombin time: 036, 040, 050, 054, 056, 078.5, 081, 082, 083, 084, 085, 086, 087, 115, 117.3, 162, 171, 174, 183, 185, 204, 205, 206, 207, 208, 250.1, 282, 283, 287.3, 331.81, 410.0–410.9, 435.3, 427.5, 447.6, 577.0, 630, 710, 747.1, 785.5, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 958.1, 958.4, 991.6, 994.1, 995.0, 996.85, V43.60–V43.69, V72.81, V72.82, V72.83, V72.84
Thyroid: 198.82, 518.5, 611.6, 780.53–780.57, 786.05, 790.6, 790.94, 793.2, 995.0, V58.0
Digoxin: 402.00, 402.10, 402.90, 414.01, 412, 414.02, 414.03, 414.04, 414.05, 414.10, 414.11, 414.19, 557.1, 746.1–746.6, 746.81–746.89, 747.22, V78.8
Fecal Occult Blood: 003.20–003.24, 003.8, 003.9, 095.4–095.9, 096, 097.0, 097.1, 097.9, 098.10–098.19, 098.2, 098.3–098.39, 098.40–098.49, 098.50–098.59, 098.6, 098.81–098.83, 098.85, 098.89, 139.0, 139.1, 751.2, V12.79, V82.8
Gamma Glutamyl Transferase: 230.0–230.6, 231.0–231.9, 232.0–232.9, 233.0–233.8, 234.0, 234.9, 790.6, V11.3
Lipids: 427.0–427.2, 427.31, 427.32, 427.41, 427.42, 427.5, 427.60–427.69, 436, 443.0, 443.1, 443.8, 443.89, 443.9, 574.00, 574.01. 574.10. 574.11, 574.20, 574.21, 574.30, 574.31, 574.40, 574.41, 574.50, 574.51, 574.60, 574.61, 574.70, 574.71, 574.80, 574.81, 574.90, 574.91, 575.2–575.8, 783.1, V67.51
Glycated Hemoglobin/Protein: 359.6
Prostate Specific Antigen: 188.8, 222.2, 584.5–584.9, 596.0–596.9, 599.1, 600, 606.0, V71.1, V76.44

Comment: One commenter submitted a list of pregnancy-related codes for addition to the codes identified as medically necessary for human chorionic gonadotropin (HCG), quantitative.

Response: In analyzing requests for additions of codes to the list, we have generally looked to the indication section of the proposed policies. The indication section of the HCG proposed policy states that HCG is useful for diagnosis of pregnancy and pregnancy-associated conditions. We note that the proposed policy is exclusively quantitative HCG (CPT code 84702). The proposed policy is not applicable for qualitative HCG. Based on review of scientific evidence, such as textbooks (Clinical Interpretation of Laboratory Tests by Frances K. Widen, M.D.) and advice of medical consultants, we believe the language in the indications of the proposed policy relative to the utility of quantitative hCG for diagnosing pregnancy is overly broad and inaccurate. Pregnancy tests for the diagnosis of pregnancy use qualitative methods of identifying HCG, rather than quantitative methods. Quantitative HCG in pregnant patients is useful to monitor patients with suspected complications of pregnancy, such as ectopic or molar pregnancy.

We believe the Committee had this understanding of the policy in that the list of covered codes included vaginal bleeding, molar pregnancy, missed abortion, ectopic pregnancy, threatened abortion, and pregnancy. Thus, the codes do not coincide with the language of the test being useful for diagnosing pregnancy. That is, codes that indicate suspected pregnancy, such as the

absence of menstruation, are not included.

Consequently, we are altering the indications for the policy for HCG in this final rule to more precisely describe the utility of quantitative HCG. The final policy will read, ''In addition, HCG is useful for monitoring pregnant patients with vaginal bleeding, hypertension and/or suspected fetal loss.'' Given this revised indication, we believe the following codes suggested by the commenter should be added to the list of codes covered by Medicare: 634.0, 636.0, 642.3, 642.4, 642.5, 642.6, 642.7, 642.9. The following codes, suggested by the commenter are not being included at this time: 623.8, 626.0, 626.1, 646.5, 658.1, 658.2, 658.3, 658.4, 659.2, 659.3, V22.2. Further, we are deleting codes V22.0 and V22.1 from the list of covered codes. These codes indicate normal pregnancy. We do not believe that quantitative HCG is reasonable and necessary for a pregnancy that is confirmed as normal.

Comment: Seventeen commenters addressed the proposed NCD on the collagen crosslinks test. Fifteen of the commenters generally expressed support for adopting the NCD on the collagen crosslinks test in the final rule but suggested clarification and revision in a number of different areas. One other commenter questioned the clinical usefulness and reliability of the test and concluded that Medicare should not reimburse it.

Another commenter did not indicate whether or not he supported the proposed national policy, but expressed the view that there were internal inconsistencies in the policy that needed to be clarified before publication in the final rule. Only one of the commenters produced scientific evidence for their views; however, much of this evidence had already been reviewed the rest of the negotiating committee and us during the deliberations.

Response: There was considerable discussion at the November 1998 meeting of the negotiation Committee on this proposed policy as well. It also noted that this was a field that was changing rapidly. We believe that the evidence available supports the policy. Since the field is rapidly changing and there are limited and inconsistent findings in the literature, it is not surprising that we received several inconsistent comments on this proposed policy. That is, some commenters believe the policy is too restrictive, and others believe it goes beyond what is supported by the science. We note, however, that most of the commenters believe that the policy is basically sound, but they were requesting refinements. After careful studying of the comments and the limited additional scientific literature submitted by the commenters, we do not believe that the public comments have presented such a radically different view as to undermine the policy we had proposed and which was recommended by the Committee.

Therefore, we are including the collagen crosslinks policy in the final rule with only minor clarification as we explain in our response to several of the more specific comments summarized below. We invite commenters to use the NCD process that was published in the April 27, 1999 **Federal Register** (64 FR 22619) to request further changes in the policy.

Comment: Some of the commenters expressed concern that the NCD on the collagen crosslinks test did not recognize that these tests may be useful in men who have degenerative bone loss. The commenters noted that while the majority of bone loss patients are women, bone loss can also affect men as well—especially those over 70 years of age.

Response: We agree that the collagen crosslinks test may be useful in assessing or monitoring the treatment regimens of men who have osteoporosis, Paget's disease, or are otherwise at risk for degenerative bone loss. We did not intend to exclude, nor do we believe that the proposed NCD should be interpreted to preclude men from coverage of collagen crosslinks tests as long as one of the applicable medical indications for coverage is met. Nonetheless, we have clarified this point in the final rule by revising the fourth sentence of the ''Indications'' section of the NCD to provide that ''Coverage for bone marker assays should be established * * * for younger beneficiaries and for those men and women who might become fast losers because of some other therapy such as glucocorticoids.''

Comment: Nine commenters indicated that the proposed NCD on the collagen crosslinks test reflects that these tests may be performed on urine, but not on serum samples. One of these commenters stated that the FDA had approved the serum-based technique as ''substantially equivalent'' to the urine-based version and offered documentation in support of adding it to the urine-based collagen crosslinks test in the final rule. Another commenter mentioned that the serum-based technique might be a more reliable test of bone turnover than the urine test, but suggested that there was insufficient information available to determine whether either test was clinically useful for monitoring drug therapy for individuals with or at risk for bone loss.

Response: We recognize that since the proposed Medicare NCD on urine-based collagen was negotiated, the FDA approved the serum collagen crosslinks test in February 1999 for the purpose of assessing or monitoring drug therapy for individuals with or at risk for bone loss. However, serum collagen crosslinks test was not part of the negotiated rulemaking. We do not believe it is appropriate to include additional tests that were not subject to negotiation in this final rule. That is, the negotiated rulemaking committee carefully selected the tests for which it wished to negotiate a coverage NCD.

The commenter noted that the FDA had determined that the serum-based technique is ''substantially equivalent'' to the urine-based version. The criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug and Cosmetic Act is significantly different from the scientific evidence we consider in making ''reasonable and necessary'' determinations under Medicare. FDA does not require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare evidence-base decisions consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage.

When sufficient clinical studies have been done on the serum tests, we encourage the commenters to use the NCD process published in the April 27, 1999 **Federal Register** to request inclusion of serum version of the test in the collagen crosslinks NCD. In the meantime, in the absence of an NCD on the serum collagen crosslink test, Medicare contractors will have local discretion in deciding whether this type of collagen crosslinks test is medically necessary for assessing or monitoring bone loss therapy.

Comment: Fifteen commenters indicated that available scientific evidence and clinical expert opinion support the view that contrary to the first paragraph of the ''Indications'' section of the proposed NCD on the coverage of collagen crosslinks tests, rapid bone loss frequently does occur

after age 65. In view of their concerns, the commenters have recommended that the first paragraph of the ''Indications section'' be deleted or substantially revised in the final rule.

Response: In response to the commenters' concerns, we re-examined the scientific evidence considered by the negotiating Committee and that was submitted during the public comment period on the collagen crosslinks proposed NCD. In the studies we reviewed, the sensitivity and specificity of the biochemical markers was relatively low, and there are wide confidence intervals associated with the results. We believe these factors demonstrate the clinical utility of biochemical markers only for patients who are rapid bone losers.

The commenters do not appear to dispute the determination that collagen crosslinks are most clinically useful only for rapid bone losers. Rather, the commenters believe that many patients over age 65 are considered rapid bone losers. While several practicing physicians indicated that in their clinical judgment patients over age 65 frequently are rapid bone losers, this clinical judgment was not supported with clinical studies to indicate the extent to which rapid bone loss may be a significant problem for Medicare beneficiaries age 65 and older.

Further, in our review of the literature, we did not find scientific evidence either supporting or disputing this assertion. In the absence of evidence to support this clinical judgment, we are not convinced that the policy negotiated by the Committee is inappropriate. In short, we find no persuasive reason to revise the proposed policy. Therefore, we believe that the first paragraph of the ''Indications'' section of the proposed NCD on this test should be included unchanged in the final rule except for the clarification discussed above with respect to men.

We would point out, however, that the age limitation is not an absolute exclusion from coverage. The language in the NCD states, ''Generally speaking, collagen crosslink testing is useful mostly in 'fast losers' of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless.'' Thus, physicians who encounter an occasional patient age 65 and over for whom they have reason to believe collagen crosslinks testing is clinically useful, may obtain Medicare coverage through documentation that the service is reasonable and necessary for that patient.

Comment: One commenter noted that there appears to be an inconsistency in the proposed NCD for collagen crosslink tests because the list of ICD–9 codes for this policy includes multiple myeloma, but this condition is not included in the ''Indications'' section for this policy. It is suggested that these two portions of the policy be made consistent.

Response: We agree that the two portions of the policy should be made consistent. The Committee operated under the ground rules that the codes included under the ''List of ICD–9–CM Codes Covered by Medicare'' should be an appropriate representation of the narrative indications. In addressing all requests for changes to the codes that were received during the comment period, we have consistently held that the codes must be a codification of a condition that was included in the indication section of the NCD. Therefore, we have removed ICD–9–CM codes 203.00 and 203.01 from the list of ICD–9–CM codes covered by Medicare for collagen crosslinks. If commenters believe this is an appropriate indication for collagen crosslinks, they may use the NCD process described in the April 27, 1999 **Federal Register** to submit scientific evidence in support of the change.

Comment: One commenter also stated that if the purpose of the proposed NCD for collagen crosslink tests is to permit this test to be used to diagnose the presence of osteoporosis or the risk of developing it, we should determine how frequently this test may be used for this purpose and whether collagen crosslinks and bone mineral density tests may be done in the same period for diagnosing osteoporosis. Otherwise, the commenter noted that the predisposing conditions for osteoporosis should be deleted as acceptable conditions for coverage of this test, and only the conditions for coverage of monitoring known osteoporosis treatment should be allowed.

Response: The purpose of the proposed NCD for the collagen crosslinks test was not to permit coverage of the test to diagnose the presence of osteoporosis or the risk of developing it. Rather, the purpose of the test, as stated in the proposed NCD, was to (1) identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored, (2) predict response (as assessed by bone measurements) to FDA-approved antiresorptive therapy in postmenopausal women, and (3) assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or at risk for osteoporosis for which treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogen receptor moderators. We are including this language unchanged in the final rule. It should be interpreted to mean that all covered indications for collagen crosslinks in the final rule relate solely to the assessment or monitoring of treatment regimens for postmenopausal women, patients with osteoporosis, Paget's disease of the bone, or others who are at risk for osteoporosis. None of the covered conditions relate to the diagnosis of osteoporosis or the risk of developing osteoporosis.

Comment: Fifteen commenters expressed the view that the proposed NCD on collagen crosslinks tests should be implemented immediately upon publication of the final rule without the 12-month delay in the effective date and the additional grace period of up to 12-months beyond the effective date called for in the March 10, 2000 proposed rule. One of the commenters stated that our reasoning in the March 10, 2000 proposed rule for the delayed implementation that referenced the need for time to allow for educational efforts and computer systems changes to be made for the various new policies was not applicable to the collagen crosslinks test for several reasons. First, the commenter suggested that the volume of Medicare collagen crosslink test claims anticipated is so negligible that the immediate implementation of the NCD on the test would not disrupt the Medicare claims process or cause related education or computer systems problems. Second, the commenter believes that the collagen crosslinks test has a unique legal status that necessitates that it be excluded from the delay in the effective date that has been proposed for all of the clinical diagnostic test NCDs that have been developed. Specifically, the commenter suggested that the collagen crosslinks test is subject to the provisions of section 4106 of the BBA, which mandated national coverage for bone mass measurements effective July 1, 1998.

Response: We continue to believe that the concerns expressed by the negotiating committee relative to the need for the delayed effective date to allow for important education and systems changes to be completed is appropriate and should be applied in the final rule to all of the 23 NCDs, including the one on collagen crosslink tests. We recognize that the volume of Medicare collagen crosslink test claims that may be anticipated may be small in comparison to the volume of Medicare

claims for the other 22 clinical laboratory tests, but the lower volume of claims expected will not preclude the need for important educational efforts and systems changes to be made for the collagen crosslinks test.

As for the commenter's suggestion that the collagen crosslinks test has a unique legal status under section 4106 of the BBA that should allow it to be excluded from the delay in the effective date of the various policies, we disagree that this is the case. Section 4106(b) of the BBA amended the law to provide that payment for bone mass measurements that are covered under the new benefit must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act. We have interpreted these provisions in the interim final rule that was published on June 24, 1998 (63 FR 34320) on coverage and payment for bone mass measurements to mean that the scope of the benefit includes bone densitometry or bone sonometry procedures that are performed with devices that have been approved or cleared for marketing by the FDA. We did not include coverage of crosslink tests within the bone mass measurement benefit. Collagen crosslink tests are, in fact, clinical laboratory tests that are paid for under the Medicare clinical laboratory fee schedule, and Medicare coverage of these tests has been addressed under section 4554 of the BBA, which, of course, mandated this negotiated rulemaking process for the coverage of certain clinical laboratory tests. Collagen crosslinks measure bone resorption and are used to monitor the effectiveness of antiresorptive therapy. We do not believe collagen crosslinks tests are appropriately considered bone mass measurements.

Comment: Ten commenters suggested that we develop a specific process for updating policies and to introduce additional national coverage decisions without having to wait for the biennial review.

Response: It is not necessary to wait for the biennial review in order to request changes in the Medicare national coverage decisions. As we noted in the preamble to the March 10, 2000 proposed rule, Medicare has announced a new process for making requests for new Medicare national coverage decisions or for requesting changes to current coverage decisions. The coverage process was delineated in a notice in the **Federal Register** published April 27, 1999, and is available on the Internet at *http://www.cms.gov/coverage/8a1.htm*

We should point out that the new coverage process includes an opportunity for members of the public to participate in coverage decisions. We post all pending coverage issues on the Internet and welcome the submission of evidence related to every issue. In addition, for some issues, we hold public meetings of the Medicare Coverage Advisory Committee (MCAC) to assist us in assessing the evidence. We have established a specific MCAC panel to address diagnostic issues, such as clinical diagnostic laboratory tests.

We intend to solicit changes in the laboratory policies biennially, as directed in section 4554 of the BBA. In addition, we will accept requests for changes to current policies at any time, as long as they comply with the requirements in the coverage notice.

Comment: One commenter was concerned that implementation of the final rule may result in denial of payment for laboratory services that are currently being paid by Medicare. The commenter suggested that a laboratory should be able to rely on the existing local medical review policies (LMRP) without fear of claims denial and potential government enforcement action until the applicable contractor changes its LMRP or until the proposed rule is effective.

Response: We agree with the commenter that the final rule should not be enforced before its effective date. Contractors should be using their existing local policies until these policies become effective. Once these national coverage decisions become effective, contractors will need to use these policies as they are published. LMRPs may not conflict with the 23 national coverage decisions outlined. If a LMRP conflicts with a national coverage decision, the contractor is required to change it so it complies with the national coverage decision. When a national coverage decision is silent on an issue, such as frequency guidance, a contractor may develop an LMRP that supplements the national coverage decision. However, the LMRP may not conflict with the national coverage decision.

Appropriate Use of Procedure Code

Comment: Three commenters expressed the view that it is not appropriate to use modifier −59 for medically necessary repeat clinical laboratory tests for the same CPT code for the same beneficiary on the same day because that modifier applies to physician procedures and not clinical laboratory tests. They indicated that modifier −91 is specifically designed for clinical laboratory tests, and is a more appropriate modifier to use in billing for medically necessary repeat tests of this type.

Response: The issue of use of modifiers −59 and −91 can be confusing. Both modifiers have a place in coding repeat clinical diagnostic laboratory tests. Modifier −91 is appropriate when in the course of treatment of the patient it is necessary to repeat the same laboratory test on the same day to obtain subsequent test results, such as when a beneficiary requires repeated blood tests that were performed at different intervals during the same day.

The commenters are correct that the new modifier −91 that was added by the American Medical Association's CPT Editorial Panel, as part of its year 2000 update, is specifically designed for the reporting of that type of repeated test. For example, if an arterial blood sample is drawn from a patient at three different intervals on the same day, and the blood testing is performed three times that same day, then CPT code 82803, Gas, blood, any combination of pH, PCO2, P02, CO2, HC03 (including calculated oxygen saturation), should be reported as follows: 82803, 82803–91, and 82803–91. We believe one of the examples provided in the March 10, 2000 proposed rule—Biochemical studies performed on different samples, for example, renins (CPT code 84244)—is an example of when the modifier −91 is appropriate.

The purpose of the Committee consensus on the use of modifier −59 was to resolve coding situations that were presented to the Committee by the microbiology community that do not meet the definition of repeated tests for which modifier −91 is appropriate. They cited situations, for example, in which samples or cultures are taken from a patient from different anatomical sites, or even different wounds, and then are tested the same day. We believe that the use of modifier −59 in reporting multiple claims submissions by a clinical laboratory for the same CPT code for the same beneficiary on the same day is the appropriate way to handle these situations and is consistent with established CPT coding conventions. We have consulted with the American Medical Association, the proprietors of the CPT coding system including modifier, in ensuring that modifier −59 is the appropriate means of indicating repeat laboratory test coding when there are two tests involving different sites. As mentioned in the preamble to the March 10, 2000 proposed rule, a few examples of appropriate use of modifier −59 would be the following:

• Multiple blood cultures (CPT codes 87040 and 87103), generally 2–3 collected from different sites to document etiology of sepsis.

• Multiple lesion samples collected from distinct anatomic sites for culture for bacteria (CPT codes 87070 and 87075).

Comment: One commenter noted that it is the experience of its organizations members that some Medicare contractors are not currently accepting the use of modifier −59, and it is suggested that we should issue an instruction to its contractors to ensure that they will accept multiple claims submitted by laboratories using modifier −59.

Response: We agree that all Medicare contractors processing laboratory claims should be accepting both modifier −59 and modifier −91 when used appropriately in billing for medically necessary laboratory services for the same CPT code for the same beneficiary on the same day, as described above in our reply to the previous comment. We will clarify the use of these two modifiers in the instructions that we will be issuing to our contractors.

Comment: One commenter indicated that there was a need for us to identify all of those clinical laboratory tests that frequently result in multiple tests being billed.

Response: We do not believe that we have the expertise or experience to attempt to identify all of the various clinical laboratory tests that might warrant the use of modifier −59. If we were to attempt this action and make errors in omission, laboratories would not be able to receive payment when it may become necessary to perform repeat testing on patients to attend to their specific medical needs. We believe that it is sufficient to provide a few examples of appropriate use of the modifier, which we will repeat in our instructional issuance.

Moreover, the Committee believes that there was not sufficient time and information available for them to attempt to identify all the various clinical laboratory tests that might warrant use of modifier −59. As a result, the Committee agreed that it would be sufficient to provide a few examples are of appropriate use of the modifier. We agree with the Committee that a few examples are sufficient to address the concern with the −59 modifier. Moreover, we believe that any attempt on our part to identify a comprehensive list of situations that would warrant the use of the −59 modifier is likely to be incomplete due to our lack of field experience and would thus generate additional concerns.

Documentation and Recordkeeping Requirements

Comment: Three commenters expressed concern about the process by which diagnostic information supporting medical necessity is to be collected from the ordering physician. Two of the commenters suggested that we publish a guideline for collecting additional information from the ordering physician. Another commenter further suggested that our guideline state the baseline effort required for obtaining documentation by the entity submitting the claim. The commenter suggested that claims should be denied only if the required effort for obtaining the documentation has been met.

Response: We acknowledge the burden that accompanies the task of collecting diagnostic information to support medical necessity. However, the Act requires that Medicare only pay for services that are reasonable and necessary. Medicare cannot pay for services that do not meet this standard simply because the laboratory has expended a specified amount of effort to obtain documentation. We have, however, identified a process for requesting documentation that we believe reduces the burden on the laboratories for collecting and submitting information to us.

As part of the negotiated rulemaking process, the Committee established a consensus to the guidelines for documentation that appeared in the preamble to the March 10, 2000 proposed rule. Specifically, the consensus statement and proposed rule provide that the laboratory is responsible for maintaining information it receives from the ordering practitioner, and the practitioner, is responsible for maintaining the information in the medical record. Our initial request for information is made to the entity submitting the claim. That entity should submit whatever documentation it has in support of the claim.

If the documentation provided by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we will take the following action: (1) Provide the ordering physician information sufficient to identify the claim being reviewed; (2) request from the ordering physician those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed; and (3) if the ordering physician does not supply the documentation requested, inform the entity submitting the claim(s) that the documentation has not been supplied and deny the claim.

Since the entity submitting the claim will be the entity to experience a payment denial if documentation does not support the medical necessity of the claim, we agreed laboratories should not be precluded from requesting additional diagnostic or other medical information from the ordering provider. In making requests for additional information, laboratories must focus their request for additional information on material relevant to medical necessity. In addition, documentation requests must take into account applicable laws and regulations related to patient confidentiality.

Comment: One commenter requested that we publish a quarterly summary that specifies the total number of tests ordered and the total number of tests not paid by Medicare due to lack of medical necessity by the ordering physician.

Response: We question the utility of quarterly reports that specify the total number of tests and total number denied due to lack of medical necessity. We fail to see how this report would assist laboratories without identification of the laboratories and/or physicians involved. Furthermore, the commenter did not identify a method of distribution of this information that would be beneficial and reasonably priced. We are not convinced that the benefits of such a report would outweigh the costs.

Laboratories are free to prepare any reports for their own use with the payment information they receive. For example, laboratories can link denial rates for failure to provide medical necessity information to specific clients and target educational efforts toward those specific problems.

Comment: Twenty-six commenters expressed concern that the March 10, 2000 proposed rule makes it possible for laboratories to be held liable for claims denial due to the lack of information supporting medical necessity. That is, the commenters were concerned that the laboratories would be the entity experiencing the loss if the physician does not submit the information supporting medical necessity. The commenters believe that the March 10, 2000 proposed rule will result in unfairness and financial hardships for the laboratory industry. Several commenters suggested that in the final rule, laboratories should not be financially responsible in this situation. Some commenters believe that the situation may be best addressed if (1) we simultaneously notify both the entity submitting the claim and the ordering physician that additional information is

being requested; (2) we tracks which physicians have failed to comply with requests for additional information; and (3) we identify a time frame that specifies when responses to requests need to be made. One commenter suggested that we create a database of medical records that service providers may access for claims purposes.

Response: The commenters do not seem to recognize that the March 10, 2000 proposed rule does not change the current provisions for liability on claims due to lack of information supporting medical necessity. Section 1862(a)(1)(A) of the Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity.

In addition, we do not agree that the provision related to denial of claims for laboratory services when documentation is not provided is unfair. Rather, we believe it would be unfair to exempt laboratories from this provision while continuing to require it for other providers and suppliers. For example, durable medical equipment (DME) suppliers frequently do not have direct contact with beneficiaries but are dependent upon physician documentation of medical need in order to receive payment.

Some commenters suggested that we simultaneously notify both the entity submitting the claims and the ordering physician that additional information is being requested. We are not accepting this suggestion for several reasons. First, in many cases, we do not have the address of the ordering physician at the time the initial request for information is made. This information will be supplied by the entity that submitted the claim following our initial request so that we can directly request additional information from the physician as is contemplated in § 410.32(d)(3)(ii). Moreover, we believe that it would be confusing to request information from both the ordering physician and laboratory simultaneously because both the laboratory and the physician could send information or both can believe that the other is handling it. Finally, duplicate mailings to both the laboratory and physician are costly to the program. This appears to be a cost without benefit.

Some commenters suggested that we track which physicians have failed to comply with requests for additional information. Similarly, this is a suggestion that would result in significant cost to the program if adopted. The commenters were not clear about how this information ought to be used. We do not agree that tracking these physicians would be beneficial. Several of the commenters suggested that we identify a time frame between a request for documentation from the carrier and denial of the claim for lack of documentation. We agree that physicians should be advised of the period of time that they have to respond to the Medicare contractor's request. Section 521 of the BIPA requires that the carrier or fiscal intermediary must make initial determinations on claims within 45 days of receipt of the claim.

Claims subject to additional information requests on prepayment review must be handled within the statutory mandated time frame. In cases for which the initial request would have been made to the entity submitting the claim before the request to the physician, it is very likely that there will be minimal time for the physician to respond. Requests for additional information made on a postpayment basis is not subject to the time frames contained in section 521 of BIPA. In issuing instructions implementing this provision of the rule, we will instruct the contractors to identify the date by which they need information on claims that have not received an initial determination and provide 60 days notice before denying a claim for failure to supply requested information when claims are identified for development based on postpayment review.

Comment: One commenter addressed the process that would allow physicians to justify additional tests that may not be deemed by local medical review policy (LMRP) as medically necessary.

Response: Most local medical review policy is written in a fashion similar to that employed by the Committee in development of the 23 national coverage decisions contained in the addendum to the March 10, 2000 proposed rule. That is, most LMRPs provide a list of codes for which medical necessity is presumed, a list of codes that are not covered, and a list of codes that are presumed not medically necessary. Contractors are required to consider any documentation that is submitted with the claim. Thus, a process already exists for physicians to justify tests that are not presumed medically necessary. Further, LMRPs are not binding upon the Administrative Law Judges that adjudicate appeals of contractor denials. Physicians may use the appeal process to seek payment for claims that the contractor determines are not justified.

Comment: One commenter requested that a form be produced that would allow physicians to justify additional clinical laboratory tests that may not be considered medically necessary by the local LMRP.

Response: Under current Medicare guidelines, clinical laboratories are already allowed, if they choose, to require that their ordering physicians use a specified medical documentation form in support of claims as the commenter has suggested. We, however, are obligated under the Paperwork Reduction Act to limit the reporting burden placed upon providers unless there is a demonstrated need for it to carry out the provisions of the applicable law and regulations. Since clinical laboratories already have the ability to require their clients to use a specified medical documentation form, we do not believe that it is necessary to require the use of such a form by all physicians for all of the tests that they order for their Medicare beneficiaries. It is possible for us to engage in this type of documentation gathering through use of a national certificate of medical necessity for clinical laboratory services. However, before we actively consider imposing this type of reporting burden on the public, we believe we need to research this proposal carefully.

Signature on Requisition

Comment: Twelve commenters addressed the March 10, 2000 proposed rule's provision about signature requirements on requisitions. Seven of the commenters were in agreement with the March 10, 2000 proposed rule provision that a signature not be required on a claim and did not submit suggestions to us. Two of the commenters requested that we publish other means of indicating that a physician has ordered a laboratory service. Three of the commenters expressed concern that the March 10, 2000 proposed rule was in conflict with CLIA requirements that a written authorization be obtained within 30 days of a verbal request for the laboratory service. One suggested that we should require USER ID instead of physician signature while another suggested that another individual who has the authority to order for the physician be required to sign the requisition in place of the physician.

Response: Regulations set forth at § 410.32(a) require that diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Some have interpreted this regulation to require a physician's signature on the requisition as documentation of the physician's order. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered. For example, the physician may document the ordering of specific tests in the patient's medical record. As stated in the preamble to the March 10, 2000 proposed rule, we will publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test.

We also do not agree with the commenters that the March 10, 2000 proposed rule conflicts with the CLIA requirements. Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) at § 493.1105, relating to the requisition, specify that a laboratory must perform services only at the written or electronic request of an authorized person. Further, this section permits oral requests for laboratory services only if the laboratory subsequently requests written authorization for the testing within 30 days.

Authorization does not equate to physician signature; the CLIA regulations provide, for example, that the patient's chart or medical record may be used as the test requisition. The CLIA regulations address this written authorization as a means of ensuring that laboratories are not performing tests that were not authorized. They do not address or conflict with the requirement that there be documentation of the physician's order available upon request of the Medicare contractor. Of course, if the physician signs the requisition himself, it would satisfy both the requirement in § 410.32(a) and § 405.1105.

Procedures for Filing Claims

The Committee discussed concerns expressed by various members of the Committee and reached a consensus on the following three issues relating to ''Procedures in Filing Claims.'' These included (1) Coding of Narrative Diagnoses, (2) Limitation on Number of Diagnoses, and (3) Matching of Diagnosis to Procedure. We received no comments from anyone on these issues.

Limitation on Frequency

Comment: Three commenters cited the lack of frequency limitations in many of the national coverage policies that had been developed in the March 10, 2000 proposed rule. Two commenters requested that we specify the allowed frequency limitations in all of the proposed policies. One commenter expressed support only for screens that are national in scope and suggested that in the absence of these national frequency limitations, local contractors should not be permitted to apply their own frequency limitations at that level.

Response: The Committee discussed this subject and agreed to set as its goal the development of specific language on frequency limitations for the various national coverage policies drafted whenever possible to promote uniformity throughout the country. The Committee spent a great deal of time and worked very diligently on this issue, but they were unable to reach a consensus on specific frequency limitations for most of the proposed national coverage policies.

We have continued to study the scientific evidence related to frequency limitations, and we do not believe that the medical evidence is sufficient to develop national frequency limitations for those policies that do not contain them at present. Further, we note that the public comments on the March 10, 2000 proposed rule did not include information supporting the addition of any specific frequency limitations to the national coverage policies. Contractors analyze data to allow them to identify what is the prevalent practice in the area. In the absence of scientific data to support national frequency limitation, we have decided to defer to local contractors in this regard who will base their determinations on the local practices.

In the absence of a national coverage policy on a particular laboratory procedure that specifies a frequency limitation, Medicare's local contractors are responsible for making individual coverage determinations on the procedure, including, if they choose, establishing appropriate local frequency limitations on the procedure.

The Committee discussed this issue and agreed that a frequency limitation would not result in a frequency-based denial at the local level unless information published by our contractor (or by us in the case of a national frequency limitation) includes an indication of the frequency that is generally considered reasonable use of that test for Medicare payment purposes. The contractor must consult with appropriate advisors, including medical specialty and other organizations, before developing and publishing frequency information for a clinical diagnostic laboratory test.

Comment: One commenter opposed the use of frequency screens that result in automatic denials and believes that the use of these screens conflicts with court cases that have held that their use contravenes the Medicare statute. The commenter believes that this type of frequency screen is used as an absolute denial mechanisms or irrebuttable presumption that forecloses the opportunity for an individualized determination of medical necessity and is, therefore, illegal. The court decisions of *Vorster* v. *Bowen,* 709 F. Supp. 934 (C.D.Cal. 1989); and *Fox* v. *Bowen,* 656 F. Supp. 1236 (D.C.Conn. 1987) are cited in support of the commenter's assertion.

Response: We believe the commenter has misunderstood the March 10, 2000 proposed rule with respect to Medicare policy on automatic denial of laboratory claims as the policy applies to frequency screens. This policy does not provide for automatic denials of laboratory claims based on frequency. Rather, under the proposed policy, contractors will provide frequency guidance before implementation of any frequency screens. Entities submitting claims for laboratory services that exceed the frequency guidance are encouraged to submit documentation of the medical necessity of the service with the claim. Contractors will review all documentation submitted before making a determination on the claim.

We do not believe that this policy is in conflict with the court cases that the commenter has referenced. On the contrary, the Court in *Vorster* expressly determined that the Medicare statute and its legislative history supported the use of utilization screens by carriers in processing claims under Part B. In that case, the plaintiff, a Medicare beneficiary, submitted claims for covered chiropractic services to the carrier that were subsequently denied entirely, based on application of a utilization screen. The plaintiff then sought a review determination from the carrier and submitted additional information to the carrier in support of her claim. The carrier again denied the claims, and the beneficiary then filed suit, alleging that the use of utilization screens was a violation of the Medicare statute.

The Court in *Vorster* rejected the plaintiff's allegation that the use of utilization screens violated the Medicare statute. According to the Court in that case: The Congress instructed the Secretary to use the expertise of private sector carriers in administering the Part B plan, and has acknowledged that the efficient administration of the Part B program includes review of utilization and the control of unnecessary utilization of covered services. [Citations omitted.]

* * * * *

Based upon the foregoing legislative history, it appears that in general, the Congress would approve the use of utilization screens in processing claims. *Vorster,* 709 F. Supp. 940–41. The Court in *Vorster* noted that the use of utilization screens would contravene the Medicare statute if they were used as ''absolute denial mechanisms'' or as ''irrefutable presumptions, which foreclosed any meaningful opportunity to receive an individualized determination of medical necessity.'' *Vorster,* 709 F. Supp. at 941. As we have stated above, however, the use of utilization screens as contemplated in the policy does *not* act as either an ''absolute denial mechanism'' or as an ''irrefutable presumption which foreclose[s] any meaningful opportunity to receive an individualized determination of medical necessity.''

We also do not think that the reasoning in the *Fox* v. *Bowen* case, also cited by the commenter, is applicable to the proposed policy. The *Fox* case involved a challenge to a denial of claims for physical therapy services to skilled nursing facility patients. A fiscal intermediary in that case had established parameters for determining whether physical therapy services would be covered for patients in skilled nursing facilities. The Court characterized those parameters as ''informal presumptions'' or ''rules of thumb,'' applied across the board ''without regard to the therapeutic requirements of the individual patient.'' Fox, 656 F. Supp. at 1248. The regulations promulgated by the Secretary, and the manual that was provided to assist intermediaries in making coverage determinations for physical therapy services, however, contemplated clearly that beneficiaries would receive an individualized assessment of need for physical therapy services. *Id.* Because an intermediary's practice in that case did not conform to the requirements of the regulations calling for an individual assessment of need for covered services, the Court in *Fox* determined that the practice was unlawful. We believe, therefore, that the *Fox* case is inapplicable to the proposed policy. The proposed policy does not constitute a denial of benefits based on ''informal presumptions'' or ''rules of thumb'' applied across the board without regard to the therapeutic requirements of the individual patient.

Comment: One commenter expressed concern that there is little oversight of the LMRP development process, which often results in LMRPs being developed without regard to our coverage guidelines. The commenter indicated that, although the Medicare Carrier's Manual requires, and the March 10, 2000 proposed rule suggests that LMRPs must be based on medical literature and current clinical practice guidelines, many are not. The commenter also stated that because there is no public notice for the development of LMRPs, there is no opportunity for beneficiaries to comment on them, and only limited opportunity for affected practitioners to do so.

Response: An LMRP is primarily a program integrity tool. It is developed to address identified or potential abuse, such as overutilization. In the absence of national policy, it is generally developed to specify criteria that describe whether the item or service is covered and under what clinical circumstances it is considered to be reasonable, necessary, and appropriate. The process for developing LMRPs includes the following: (1) Development of a draft policy based on review of medical literature and the contractor's understanding of local practice; (2) soliciting comments from the medical community, including the Contractor Advisory Committee (CAC); (3) responding to and incorporating into a final policy the comments received; and (4) notifying providers of the policy's effective date.

In accordance with our instructions to contractors, LMRPs must be based on the strongest evidence available. The initial action in gathering evidence in developing an LMRP must always be a search of published scientific literature for any available evidence pertaining to the item or service in question. We instruct contractors to heavily weigh published authoritative evidence derived from randomized clinical trials or other definitive studies. We also instruct contractors to consider as evidence the consensus of expert medical opinion (that is, recognized authorities in the field) or medical opinion derived from consultation with medical associations or other health care experts. We do advise them, however, that acceptance by individual providers or groups of providers does not normally indicate general acceptance by the medical community. Testimonials and limited case studies distributed by sponsors with a financial interest in the outcome is not sufficient evidence of general acceptance by the medical community.

Contractors are required to provide a minimum comment period of 45 days on proposed LMRPs. The 45-day period begins with distribution to the CAC. Contractors are required to make their CAC meetings open to the public, and all interested parties, including beneficiaries, may attend and comment on the proposed policies. Further, the proposed policy is not only distributed to the CAC, but also to representatives of specialty societies, other than those represented on the CAC, when appropriate. Contractors are instructed to remain sensitive to other organizations or groups, which may have an interest in an issue. All comments received are considered and responded to either through the contractor's newsletter or individually to the commenter. The final policy is announced in a contractor bulletin at least 30 days before implementation.

Our regional staffs review the contractors' performance annually. If the commenter has specific details regarding a contractor that is not following the above requirements in the development of its local policies, they should notify us so that it can be investigated.

Comment: Three commenters expressed concern with limitations that might be imposed by the provision for automatic denial for egregious utilization.

Response: After considering the comments, we believes that the March 10, 2000 proposed rule was not sufficiently detailed in respect to this provision to benefit from public comment. Consequently, we are withdrawing the provision of automatic denial for egregious utilization and will study the matter further.

Comment: One commenter believes that the use of frequency screens that results in automatic denials will lead to underutilization of Medicare-covered medically necessary services by encouraging laboratories to give Advance Beneficiary Notices (ABNs) in every situation.

Response: The commenter appears to have misunderstood the March 10, 2000 proposed rule with regard to automatic denials. The proposed policy severely limits automatic denial based on frequency. The proposed policy, which we are incorporating in this final rule, provides that, except in limited and specified circumstances as described in

these regulations, we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim. For example, before denying a claim, contractors must review and consider justifications prepared by a provider or supplier, primary and secondary diagnosis, and copies of medical records that are submitted with the claim. Contractors may automatically deny a claim without any manual review only if a national coverage decision or LMRP specifies the circumstances under which a service is denied and those circumstances exist, or the service is specifically excluded from Medicare coverage by statute.

We do not believe that application of a Medicare policy on automatic denial of laboratory claims, as described in these regulations, will result in the underutilization of Medicare covered services as the commenter suggested. To the extent that laboratories and physicians may issue additional ABNs to these patients that they would not do otherwise, we believe that this may, in fact, be helpful to beneficiaries. The purpose of the ABN is to give beneficiaries advance notice that a service may not be covered so that they have the opportunity to make an informed choice on whether to have the service or not.

Comment: Four commenters offered suggestions for how the Medicare policy on Advance Beneficiary Notices (ABNs) should be clarified with respect to situations when laboratory tests that are performed exceed frequency limitations. They also made suggestions regarding when ABNs need to be signed by beneficiaries under the Medicare limitation on liability provisions.

Response: As we indicated in the preamble to the March 10, 2000 proposed rule, section IV, Other Topics Discussed by the Committee, the Medicare provisions on limitation on liability (sometimes called waiver of liability) were identified as falling outside the scope of the clinical laboratory negotiations. The limitation on liability provisions (including the related subject of ABNs) are currently found in section 1879 of the Act; 42 CFR part 411, subpart K; section 7330.5.A of the Medicare Carriers Manual; sections 3440 through 3446.9 of the Fiscal Intermediary Manual, and any currently applicable rules. Revised Part B ABNs, including one specifically relating to providers of clinical laboratory services, have been circulated in the Paperwork Reduction Act public comment process since October 26, 2000. All interested parties have had the opportunity to comment on those revised notices.

Comment: One commenter believes that a laboratory should be required to track frequencies only for tests performed for beneficiaries by the clinical laboratory itself and requests that we confirm this in the final rule.

Response: We do not place any requirements on laboratories to track frequencies of tests used by Medicare beneficiaries they serve, whether those services are furnished by a single laboratory or are performed by other laboratories.

Comment: One commenter suggested that laboratories should be allowed to bill the patient for frequency denials regardless of whether an ABN has been issued to the beneficiary.

Response: Under section 1879(a) and (b) of the Act, a provider of clinical laboratory services may bill a Medicare beneficiary for its services that are denied Medicare payment due to lack of medical necessity only if the laboratory informed the patient, before furnishing the service, that Medicare was likely to deny payment for the service. Frequency based denials are made because a contractor has determined that it is not reasonable and necessary for a beneficiary to receive that quantity of services based on the documentation that is presented with the claim. Therefore, the statute does not permit us to authorize laboratories to bill a beneficiary for the services that are denied based on frequency unless the beneficiary has been advised of the potential denial.

Comment: One commenter asked why hospitals performing laboratory tests for outpatients are not allowed to ask their Medicare patients to sign ABNs in circumstances when Medicare coverage is uncertain due to medical necessity considerations.

Response: Since the proposed rule was published on March 10, 2000, we have clarified our Medicare policy on the use of Part B ABNs by hospitals that perform laboratory tests and other Part B services. On July 27, 2000, we issued a Program Memorandum (PM) (PM A–00–43) to our Medicare contractors that explicitly provides for the use of the current Part B ABN in the institutional setting.

Comment: One commenter noted that claims for laboratory services that exceed frequency limitations can only be read by the Medicare contractors if they are able to image attachments that come with the first claim submission. The commenter suggested that we make certain that all of our Medicare contractors image and review attachments submitted with initial claims.

Response: All Medicare contractors have the capability to image hard copy documentation that is submitted with the claim. Unless the claim is suitable for auto-denial because the national of local policy specifies the circumstances under which the service is denied or the service is specifically excluded from Medicare coverage by law, contractors are required to review any such documentation before making a determination on the claim (See section 5.1 of the Program Integrity Manual.)

Comment: One commenter suggested that when Medicare clinical laboratory test specimens are being referred to multiple laboratories, contractors should develop claims that exceed the frequency parameters before denial. Specifically, the commenter proposed the following three-step approach: (1) Use prepayment methods to scrutinize the laboratories involved, particularly those that have billing profiles known to be suspect; (2) directly contact the ordering physicians by mail, suggesting that they review the billing and medical necessity of the tests; and (3) encourage physicians to share laboratory reports among all physicians participating in the care of their respective patients.

Response: In response to our specific request for new ideas on how to respond to the multiple laboratory problems discussed by the Committee and described in detail in the March 10, 2000 proposed rule, the commenter offered several interesting suggestions for doing this, but generally the suggestions are not new ones. As we indicated in the March 10, 2000 proposed rule, it would be very costly for our contractors to undertake the developmental work on clinical laboratory claims that would be required to use the prepayment methods proposed by the commenter. At present, laboratories and ordering physicians are free to submit medical justification that our contractors are required to consider. However, we cannot commit to the development of every claim before a denial based on excessive frequency in the fashion suggested by the commenter. We agreed to require contractors to publish frequency limitation guidance to laboratories and physicians in advance of their use as screens in the claims review process. We recognize that physicians and laboratories may not be aware of the number of times that a given beneficiary has had testing performed during a particular time period due to the use of multiple providers. We do, indeed, encourage physicians to share their patients' laboratory reports with other physicians participating in the care of their

patients, particularly those to whom they make referrals.

Comment: Ten commenters responded to the Committee's request regarding informing beneficiaries of frequency denials by expressing concern that without a Medicare database available, clinical laboratories will be unable to identify patients who are reaching the frequency limitation and, thus, will be unable to inform patients of possible claims denials. Seven of the ten commenters suggested that Medicare provide timely access to the Common Working File (CWF) for monitoring frequencies. Two of the ten commenters suggested that any information-sharing system that relies upon mailing paper notices to beneficiaries to share with their physicians would be inefficient and administratively burdensome to Medicare as well as confusing to beneficiaries. They requested instead that Medicare develop a comprehensive database, ideally electronic, containing patient-specific laboratory test frequency information.

Response: We cannot adopt any of the database proposals for several reasons. Several Committee members during the negotiations suggested similar proposals for notifying beneficiaries of frequency denials and requesting that they advise their physicians of the denials in an effort to encourage their physicians to obtain ABNs. We believed then, and continue to maintain, that it would not be possible for us to implement any of the notification proposals because of the high cost to Medicare. In addition, we believe that even the most sophisticated systems that might be available in the next few years would be likely to inaccurately identify potential denial situations due to time lags between receipt of services. Since the Committee could not agree to a specific proposal for dealing with the problem raised, we did agree to solicit in the March 10, 2000 proposed rule new ideas—especially ideas that included shared responsibility—for addressing this problem from Committee members as well as others. Unfortunately, the database proposals described above do not meet the parameters for shared responsibility that we were seeking, but instead would place a disproportionate responsibility and cost on the Medicare program.

We will continue to consider ideas for assisting Medicare beneficiaries become aware of potential overutilization of clinical diagnostic laboratory testing while protecting the privacy of their medical information. If we discover a mechanism that ensures privacy protections, accurately reflects current proximity to frequency expectations, and is easy for beneficiaries to understand, we will implement the system expeditiously.

Comment: One commenter suggested that the Explanation of Medicare Benefits (EOMB) should indicate to the beneficiary when a frequency limit has been exceeded. In this way, the beneficiary would know that future services for the same test may potentially be denied.

Response: The Committee discussed a similar suggestion. We expressed concern that the proposal would be costly to implement with little assurances that it would be beneficial. Several members of the Committee acknowledged that beneficiaries are not likely to remember the specific tests for which they have received frequency notification nor are they likely to take their EOMB with them when they visit their physician. Thus, we believe we are not likely that notification of beneficiaries in the EOMB would be helpful.

Moreover, frequency screens are applied over a period of time. For example, a contractor may set a frequency screen of four glycated hemoglobin tests per year. However, neither the beneficiary nor the physician is likely to know when the base period is reset, making the notification no longer applicable. Thus, it is possible that armed with incomplete or outdated information, a beneficiary may not be offered a medically necessary test or may decline a medically necessary test because he/she believes the test would not be covered. Consequently, we are not adopting this suggestion because we believe it not only would not be cost-effective, but it has a high risk of having harmful effects on Medicare beneficiaries.

Effective Date

Comment: Several physicians who commented expressed concern with the 12-month delay in effective date proposed in the March 10, 2000 proposed rule. They were particularly interested in earlier implementation of the coverage policies. The commenters urged us to consider earlier implementation, but they did not address the ability of the industry to implement the system changes associated with these policies or the impact of denials upon laboratories if physicians who have not been educated to the policies, order tests for conditions that are not presumed to be reasonable and necessary without submitting medical justification.

Response: The Committee recommended a 12-month delay in the effective date of the rule for several reasons. First, the Committee was concerned that some of the policies involved changes in the computer systems of the entity they represented. The Committee noted that it is not possible for most laboratory, hospital, and physician office computer systems to be modified to accommodate changes quickly. It would not be possible for the industry to be prepared for implementation with only 90 days notice. Second, the Committee noted that a large volume of laboratory claims (approximately 60 percent) is potentially affected by the national coverage decisions.

The Committee expressed concern that implementation of the policies without an adequate prior period of education of the physician and laboratory community could result in a significant volume of denied claims without an opportunity to recover payment from beneficiaries. The Committee voluntarily planned an ambitious educational program and expressed a desire that the policies provide an adequate opportunity to engage those educational activities before implementation. Consequently, the Committee proposed a 12-month delay in effective date.

We believed then, and continue to believe, that the concerns expressed by the many members of the negotiating Committee related to education and system changes are valid and that the delayed effective date of policies that require system changes or educational efforts is necessary and appropriate. Therefore, we are not accepting the commenters' suggestion to move up implementation of the NCDs for laboratory services.

However, we note that a number of provisions that are discussed in the preamble to the March 10, 2000 proposed rule are not likely to require changes to computer systems nor is their implementation likely to result in a significant volume of claims denials if they are implemented without an extended period of prior notice.

Instead, they entail clarification of our policies with regard to processing claims for clinical laboratory tests. For example, we agreed to issue instructions requiring contractors to provide frequency guidance before use of frequency screens, clarify that we do not require a signature to be submitted with claims, and clarify coding guidelines for reporting multiple procedures, etc. These provisions are essentially clarifications of our existing policies and issuing the clarifications sooner as opposed to later will significantly improve the working relationship

between some laboratories and Medicare claims processing contractors. In addition, issuance of these clarifications will restore confidence to laboratories who may have in the past acted in accordance with these policies but, because there has been lack of consistency in the interpretations, are fearful that they will later be advised that the claims are in error and subject to recovery of payment. Moreover, early implementation of these clarifications will result in more rapid consistency among the Medicare contractors in application of our administrative policies for laboratories, which is one of the primary objectives of the legislation (section 4554(b) of BBA) authorizing this rule. Finally, we believe that some of the provisions, such as requiring notice of utilization guidelines before implementation of frequency screens, hold universal benefit to the laboratory industry that should be available as soon as possible.

We do not believe that earlier implementation of these clarifications will adversely affect laboratories. Therefore, provisions of the rule that are not likely to require system changes or result in a significant volume of claims denials if implemented without an extended period of education, will be effective February 21, 2002, and we will issue the program instructions within 90 days of publication of the final rule. We believe that this includes the following provisions related to:

- Clarification that the administrative policies discussed in the preamble to the March 10, 2000 proposed rule and the NCDs in the addendum to the March 10, 2000 proposed rule apply equally to all clinical diagnostic laboratory tests payable under Part B regardless of setting (hospital and nonhospital). (See preamble section III and §410.28 and 410.32 of this final rule.)
- Clarification that use of the term ''screening'' or ''screen'' in a CPT code descriptor does not necessarily describe a test performed in the absence of signs or symptoms of illness, disease or condition. (See preamble section III.C.1.)
- Clarification of the use of modifier codes to indicate multiple services that are medically necessary to diagnose or treat the beneficiary's condition. (See section III.C.2. of the preamble.)
- Clarification that the signature of the ordering physician is not required for Medicare purposes on a laboratory test requisition. (See section III.D.3 of the preamble.)
- Clarification that appropriate diagnosis codes may be assigned to a narrative, even if wording of the narrative does not exactly match the code descriptor for the ICD–9–CM code. (See section III.E.1 of the preamble.)
- Clarification that laboratories may use the narrative field on the claims to report additional diagnoses if the Medicare contractor's system will not accept all of the codes in the diagnoses field. (See section III.E.2 of the preamble.)
- Clarification that in the absence of matching diagnosis to procedure codes supplied by the laboratory, Medicare contractors will examine all submitted codes on prepayment review, taking into account program integrity. (See section III.E.3 of the preamble.)
- Clarification that Medicare contractors will not use a frequency screen that could result in a frequency-based denial unless the contractor has published information about the appropriate frequency for the service or unless we have published information about the appropriate frequency in a national coverage decision. (See section III.F.1 of the preamble.)
- Codification of the existing policy that Medicare will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim. (See section III.F.2 of the preamble and §410.32(d)(4) contained in this final rule.) Remaining provision of the rule, which are primarily provisions that are likely to involve system changes and require educational efforts to avoid erroneous denial of claims, will become effective November 25, 2002. These provisions include:
- Date of service (section III.A.3 of the preamble).
- Use of consistent remittance message (section III.F.4 of the preamble.
- National coverage decisions (addendum).
- Maintenance and submission of documentation (section III.D.1 and 2 of the preamble and §410.32(d)(2) and (d)(3)).

The effective dates for changes made to the CFR as described in this rule are as follows:

- Sections 410.28 (f) and section 410.32(e), which provide for equal application of the rules relating to laboratory service to hospital and CAHs, are effective February 21, 2002.
- The redesignation of paragraphs in §410.32(d) is effective February 21, 2002.
- Section 410.32(d)(2) and (d)(3), which specifies documentation and recordkeeping requirements and claims review procedures, are effective November 25, 2002.
- Section 410.32(d)(4), which provides for review of information submitted with a claim before denial for utilization parameters unless a national of local policy on the service exists, is effective February 21, 2002.

IV. Summary of Changes to the Proposed Rule

The proposed rule stated that the policies would be applicable to all laboratory tests ''billed under Medicare Part B, regardless of the location * * * (Physicians' office laboratories, hospital laboratories, independent laboratories, etc., or of the type of Medicare contractor processing the claims (carriers or fiscal intermediaries).'' 65 FR 13084. In order to make the policies applicable to all settings, Centers for Medicare & Medicaid Services is revising § 410.28 and § 410.32 to clarify the applicability of the provisions of this rule to hospitals and CAHs providing tests covered under Part B to outpatients.

1. We are adding the following codes to the list of codes covered by Medicare in the various policies:

Blood glucose: 780.31, 781.0, 783.6
Digoxin: 429.2, 972.0
Fecal Occult Blood Test: 003.0, 003.1, 095.2, 095.3, 098.0, 098.7, 098.84, 139.8, 159.0–159.9, 569.82, 569.83, 596.1, 751.1
Gamma Glutamyl Transferase: 230.7, 230.9, 642.5, 782.4, 789.1, 790.4, 790.5, V42.7
Lipids: 278.00, 401.0–401.9, 402.00–402.91, 403.00–403.91, 404.00–404.93, 405.01–405.99, V42.7
Prostate Specific Antigen: 236.5, 599.6, 788.30, 788.41, 788.43, 788.62
Human immunodeficiency virus testing (Diagnosis): 263.0, 263.1, 263.9, 486
Partial thromboplastin time: 362.30, 362.31, 362.32, 362.33, 362.34, 362.35, 362.36, 362.37, 410.0–.9, 456.8, 530.82,
Prothrombin time: 786.50, V12.51–V12.59
Iron Studies: 579.8, 579.9, 713.0, 716.4–716.9, V56.0, V56.8
Thyroid: 290.3, 297.1, 333.99, 358.1, 359.5, 376.21, 376.22, 425.7

2. We are removing the paragraph regarding denial of claims for services using devices that require, but do not have, FDA approval from the reasons for denial section of all 23 policies. Under the national coverage decision regarding clinical trials, certain items that require but do not have FDA approval may be covered.

3. We are amending the NCD on collagen crosslinks by adding a clarification that both men and women may receive the test. We are also deleting codes 203.00 and 203.01 from the list of ICD–9–CM codes that are covered by Medicare, as this diagnosis is not included in the indication section of the policy.

4. We are modifying the policy for Gonodotropin, chorionic (HCG); quantitative to clarify that the test is not useful for diagnosing pregnancy.

5. We are deleting the language proposed for inclusion in § 410.32(d)(4) on automatic denial and manual review that relates to egregious overutilization.

6. We are changing the effective date for certain provisions of the rule from that proposed. The following provisions are effective February 21, 2002, and we will issue the program instructions within 90 days of publication of the final rule. We believe that this includes the provisions related to the following:

• Clarification that laboratory policies apply equally to all laboratories (hospital and nonhospital) as contained in section III of the proposed rule, and §§ 410.28(f) and 410.32(e) of this final rule.

• Clarification of codes that use the word ''screening'' in the descriptor as contained in section III.C.1 of the proposed rule.

• Clarification of coding of multiple tests as contained in section III.C.2 of the proposed rule.

• Clarification the signature is not required on requisition as contained in section III.D.3 of the proposed rule.

• Clarification of coding narrative diagnoses as contained in section III.E.1 of the proposed rule,

• Clarification on the number of diagnoses on a claim as contained in section III.E.2 of the proposed rule.

• Clarification on diagnosis and procedure code matching as contained in section III.E.3 of the proposed rule.

• Publishing frequency guidance before implementing screens as contained in section III.F.1 of the proposed rule.

• Reminder of auto denial policies as contained in section III.F.2 of the proposed rule, and § 410.32(d)(4).

• Consistency in remittance messages as contained in section III.F.4. of the proposed rule.

Provisions that will become effective November 25, 2002 include the following:

• Date of service as described in section III.A.3. of the proposed rule.

• Use of consistent remittance message as described in section III.F.4 of the preamble.

• National coverage decisions as described in the addendum.

• Requesting documentation directly from ordering practitioner as described in section III.D.2 of the proposed rule and §§ 410.32(d)(2) and (d)(3) of this final rule.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Documentation and Recordkeeping Requirements

In summary, § 410.32(d)(2)(i) requires the physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service to maintain documentation of medical necessity in the beneficiary's medical record.

While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

Submitting the Claim

In summary, § 410.32(d)(2)(ii) requires an entity submitting the claim to maintain the following documentation:

• The documentation that it receives from the ordering physician.

• The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician.

While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

Entity Request for Additional Information

In summary, § 410.32(d)(2)(iii) requires that an entity submitting a claim may request additional diagnostic and other information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

The burden associated with this requirement is the time and effort for the physician or qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section, who orders the service, to disclose additional diagnostic and other information to the entity submitting the claim that demonstrates that the services it bills are reasonable and necessary. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

Claims Review: Documentation Requirements

In summary, § 410.32(d)(3)(i) requires that an entity submitting a claim provide to Centers for Medicare & Medicaid Services upon request; (1) documentation of the physician's order for the service billed (including information sufficient to enable Centers for Medicare & Medicaid Services to identify and contact the ordering physician), (2) documentation showing accurate processing of the order and submission of the claim, and (3) any diagnostic or other medical information supplied to the laboratory by the ordering physician, including any ICD–9–CM code or narrative description supplied.

In summary, § 410.32(d)(3)(iii) authorizes the entity submitting the claim to request additional diagnostic and other medical information that is relevant to the medical necessity of the specific services from the ordering physician consistent with applicable patient confidentiality laws and regulations.

Since these reporting requirements would be imposed under the conduct of an administrative action and/or audit, these requirements are not subject to the PRA as defined under 5 CFR 1320.4(a)(2).

If you have any comments on any of these information collection and recordkeeping requirements, please mail the original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group, Division of Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850l. Attn: John Burke 3250–F; and Office of Information and

Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, Desk Officer.

VI. Regulatory Impact Analysis

We have examined the impacts of this final rule as required by Executive Order (EO) 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

Section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

A. Executive Order 12866

The intent of this final rule is to promote program integrity and national uniformity and simplify administrative procedures for clinical diagnostic laboratory services. We do not expect the provisions of this final rule to have a significant cost effect upon providers or suppliers. The provisions of the final rule, for the most part, are administrative and state explicitly and codify practices that are currently in effect. That is, physicians maintain documentation in the medical record and laboratories maintain the information that is provided to them. We expect no cost consequence of codifying this common practice.

Similarly, we do not anticipate a cost effect of the provision related to the documentation that must be submitted upon claims review. While some Medicare contractors presently request medical record information directly from laboratories, the laboratories must in turn seek the information from the physicians. Requiring Medicare contractors to seek medical record information directly from physicians may result in a minimal increase in the administrative cost of conducting claims review. We anticipate that there would be offsetting savings from reduced Medicare contractor requests to laboratories for documentation. This would result in a decreased documentation burden to the laboratories.

The provision in § 410.32(d)(4) merely codifies policies that are presently included in the Medicare program manuals. Since these provisions are currently operational, there is no cost effect to their codification. The national coverage decisions published as Addendum B to this final rule potentially may give rise to a cost effect. Approximately 60 percent of the total volume of laboratory claims would be subject to a national coverage decision. Implementation of the national coverage decisions would result in some adjustments in the amount and degree of coverage (that is, there would be some increases and some decreases). However, we do not have data available to precisely quantify the amounts involved. We estimate that the net cost effect of these coverage decisions would not be significant.

If there is currently an LMRP for a test for which we issue a national coverage decision, and the LMRP was more liberal than the national coverage decisions, this will result in cost savings to the Medicare program. If an LMRP was more restrictive than a national coverage decision, it will result in a cost increase for the Medicare program. After careful analysis of the information available regarding LMRPs, we estimate that the costs and savings are likely to offset each other, and that the national coverage decisions will have a negligible cost impact.

We should point out, however, that clinical diagnostic laboratory services are considered as part of the calculation of the sustained growth factor used in determining changes in the Medicare payment amounts under the Medicare physician fee schedule. Should there be a significant increase in Medicare payment for laboratory services, Medicare may recover these costs through reductions in the otherwise applicable physician payments.

B. The Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. As noted above, we do not anticipate that this final rule will have a significant cost impact. Thus, we certify that this final rule will not result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector of $110 million.

C. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million to $25 million or less annually (see 65 FR 69432). Intermediaries and carriers, physicians, and many laboratories are considered small entities.

This final rule will affect all clinical laboratories located in physician offices, hospitals, other health facilities, Medicare contractors, and independent laboratories. There are approximately 160,000 labs affected. We believe the impact of this final rule on these entities, for the most part, will be positive.

As stated above, this final rule will, for the most part, explicitly state and codify existing policies. Having a clear statement of policies will be beneficial to entities submitting Medicare claims because they can avoid unintentional errors. The provision relating to Medicare seeking medical record information directly from physicians will reduce the burden of recordkeeping and reporting on laboratories without increasing the burden on physicians. Publication of clear and consistent national coverage decisions will assist physicians and laboratories in knowing in advance situations in which additional documentation may be needed to support payment on a claim. The documentation may be submitted with the initial claim, thus avoiding the increased cost of appealing a denied claim. National coverage decisions relating to laboratory claims will result in consistent coverage determination regardless of geography, and, consequently, less confusion for beneficiaries, who often do not understand the present situations of coverage for a service in one area and not in other areas. Reduced confusion for the beneficiary results in reduced inquiry workloads for Medicare contractors.

As noted above, there may be some areas where implementation of the national coverage decisions will result in denial of payment in situations in which payment is presently made. We

believe that the policies, developed in partnership with the physician and laboratory community and based on authoritative evidence, reflect the appropriate treatment of clinical diagnostic laboratory services. Thus, to the extent that payment is presently being made for these services, we believe it is inappropriate and should be curtailed.

We do not expect any beneficiary to be deprived of medically necessary services as a result of these provisions. Nor do we expect that there will be an impact upon the availability of covered services to beneficiaries. Beneficiaries may, however, experience a minimal increase in out-of-pocket costs if they choose to have testing that is not covered by Medicare. That is, publication of clear decisions regarding when a test is considered medically necessary may prompt physicians and laboratories to execute advanced beneficiary notices and charge patients for noncovered services, when they may not have followed these procedures due to ambiguity regarding whether the service will be covered by Medicare.

For these reasons, the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this regulation.

We have reviewed this rule under the threshold criteria of Executive Order 13132. We have determined that it does not significantly affect States' rights, roles, and responsibilities.

List of Subjects in 42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services amends, 42 CFR chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. A new paragraph (f) is added to § 410.28 to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

3. In § 410.32:

A. Paragraphs (d)(1) through (d)(7) are redesignated as paragraphs (d)(1)(i) through (d)(1)(vii);

B. Paragraph (d) introductory text is redesignated as paragraph (d)(1) introductory text, and a heading is added; and

C. Paragraphs (d)(2) through (e) are added to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(d) *Diagnostic laboratory tests.* (1) *Who may furnish services.* * * *

(2) *Documentation and recordkeeping requirements.*

(i) *Ordering the service.* The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* The entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.* (i) *Documentation requirements.* Upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital

Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 11, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

Dated: October 9, 2001.

Tommy G. Thompson,

Secretary.

Addendum A—Introduction to National Coverage Policies for Diagnostic Laboratory Tests

Purpose

This addendum provides an introduction to national coverage policies for diagnostic laboratory tests payable under Part B of Medicare. This addendum explains what a national coverage policy is, what effect a national coverage policy has, and describes the various sections in the policies. In addition, it explains the two approaches used to develop these national coverage policies.

What Is a National Coverage Policy?

Part B of title XVIII of the Social Security Act (the Act) provides for Supplementary Medical Insurance (SMI) for certain Medicare beneficiaries, specifying what health care items or services will be covered by the Medicare Part B program. Diagnostic laboratory tests are generally covered under Part B, unless excluded from coverage by the Act. Services that are generally excluded from coverage include routine physical examinations and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. A test may be considered medically appropriate, but nonetheless be excluded from Medicare coverage by statute.

A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice. Words such as ''may be indicated'' or ''may be considered medically necessary'' are used for this reason. Where a policy gives a general description and then lists examples (following words like ''for example'' or ''including''), the list of examples is not meant to be all-inclusive but merely to provide some guidance.

What Is the Effect of a National Coverage Policy?

A national coverage policy to which this introduction applies is a National Coverage Decision (NCD) under section 1862(a)(1) of the Social Security Act. Regulations on National Coverage Decisions are codified at 42 CFR 405.732(b)–(d). A Medicare contractor may not develop a local policy that conflicts with a national coverage policy.

What Is the Format for These National Coverage Policies?

Below are the headings for national coverage policies, developed by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests.

Medicare National Coverage Decision

This section identifies the official title of the policy.

Other Names/Abbreviations

This section identifies other names for the policy. It generally reflects more colloquial terminology.

Description

This section includes a description of the test(s) addressed by the policy and provides a general description of the appropriate uses of the test(s).

HCPCS Codes

The descriptor(s) used in this section is (are) the Current Procedural Terminology (CPT) or other CMS Common Procedure Coding System (HCPCS). The CPT is developed and copyrighted by the American Medical Association (AMA). If a descriptor does not accurately or fully describe the test, a more complete description may be included elsewhere in the policy, such as in the *Indications* section.

Indications

This section lists detailed clinical indications for Medicare coverage of the test(s).

Limitations

This section lists any national frequency expectations, as well as other limitations on Medicare coverage of the specific test(s) addressed in the policy—for example, if it would be unnecessary to perform a particular test with a particular combination of diagnoses.

ICD–9–CM Codes Covered by Medicare Program

This section includes covered codes—those where there is a presumption of medical necessity, but the claim is subject to review to determine whether the test was in fact reasonable and necessary. The diagnosis codes are from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). Where the policy takes an ''exclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM code sections below.''

Reasons for Denial

This section includes standard language reflecting national policy with respect to all tests— such as denial of screening services and denial if medical necessity is not documented in the patient's medical record. This section may also include reasons for denial related to the specific test(s). This section was not negotiated by the Negotiated Rulemaking Committee, but rather reflects CMS policy.

ICD–9–CM Codes Denied

This section lists codes that are never covered. If a code from this section is given as the reason for the test, the test may be billed to the Medicare beneficiary without billing Medicare first because the service is not covered by statute, in most instances because it is performed for screening purposes and is not within an exception. The beneficiary, however, does have a right to have the claim submitted to Medicare, upon request.

ICD–9–CM Codes That Do Not Support Medical Necessity

This section lists/describes generally non-covered codes for which there are only limited exceptions. However, additional documentation could support a determination of medical necessity in certain circumstances. Subject to section 1879 of the Social Security Act (the Act), 42 CFR 411, subpart K, section 7330 of the Medicare Carriers Manual section 3440–3446.9 of the Medicare Fiscal Intermediary Manual and any applicable rulings, it would be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the beneficiary. Where the policy takes an ''inclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.''

Sources of Information

Relevant sources of information used in developing the policy are listed in this section.

Coding Guidelines

This section includes coding guidelines that apply generally to all policies, as well any additional coding instructions appropriate for a specific national coverage policy. The coding guidelines may be from or based on a Coding Clinic for ICD–9–CM published by the American Hospital Association.

Documentation Requirements

This section refers to documentation requirements for clinical diagnostic laboratory tests at 42 CFR 410.32(d) and includes any specific documentation requirements related to the test(s) addressed in the policy.

Other Comments

This section may contain any other relevant comments that are not addressed in the sections described above.

What Are the Two Approaches Used in Developing a National Coverage Policy?

To develop national coverage policies for the tests assigned to each Workgroup, the Committee agreed to use one of two approaches, referred to as ''inclusionary'' and ''exclusionary''. Policies using the ''inclusionary'' approach list the ICD–9–CM codes in the following two categories: ICD–9–CM Codes Covered by Medicare Program and ICD–9–CM Codes Denied. These policies do not list the codes that require additional documentation to support medical necessity.

The exclusionary approach was used for tests for which local medical review policies had identified a large number of acceptable ICD–9–CM codes. The Committee used this approach to develop a proposed policy on blood counts. In lieu of listing all the ICD–9–CM codes that support medical necessity of a test or group of tests, policies using the ''exclusionary'' approach list ICD–9–CM codes in the following two categories: ICD–9–CM Codes Denied and ICD–9–CM Codes That Do Not Support Medical Necessity.

Addendum B—National Coverage Decisions

Medicare National Coverage Decision: Culture, Bacterial, Urine

Other Names/Abbreviations: Urine culture

Description

A bacterial urine culture is a laboratory procedure performed on a urine specimen to establish the probable etiology of a presumed urinary tract infection. It is common practice to do a urinalysis prior to a urine culture. A urine culture may also be used as part of the evaluation and management of another related condition. The procedure includes aerobic agar-based isolation of bacteria or other cultivable organisms present, and quantitation of types present based on morphologic criteria. Isolates deemed significant may be subjected to additional identification and susceptibility procedures as requested by the ordering physician. The physician's request may be through clearly documented and communicated laboratory protocols.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
87086	Culture, bacterial, urine; quantitative, colony count
87087	Culture, bacterial, urine; commercial kit
87088	Culture, bacterial, urine; identification, in addition to quantitative or commercial kit
87184	Sensitivity studies, antibiotic; disk method, per plate (12 or fewer disks)
87186	Sensitivity studies, antibiotic; microtiter, minimum inhibitory concentration (MIC), any number of antibiotics

Indications

1. A patient's urinalysis is abnormal suggesting urinary tract infection, for example, abnormal microscopic (hematuria, pyuria, bacteriuria); abnormal biochemical urinalysis (positive leukocyte esterase, nitrite, protein, blood); a Gram's stain positive for microorganisms; positive bacteriuria screen by a non-culture technique; or other significant abnormality of a urinalysis. While it is not essential to evaluate a urine specimen by one of these methods before a urine culture is performed, certain clinical presentations with highly suggestive signs and symptoms may lend themselves to an antecedent urinalysis procedure where follow-up culture depends upon an initial positive or abnormal test result.

2. A patient has clinical signs and symptoms indicative of a possible urinary tract infection (UTI). Acute lower UTI may present with urgency, frequency, nocturia, dysuria, discharge or incontinence. These findings may also be noted in upper UTI with additional systemic symptoms (for example, fever, chills, lethargy); or pain in the costovertebral, abdominal, or pelvic areas. Signs and symptoms may overlap considerably with other inflammatory conditions of the genitourinary tract (for example, prostatitis, urethritis, vaginitis, or cervicitis). Elderly or immunocompromised patients, or patients with neurologic disorders may present atypically (for example, general debility, acute mental status changes, declining functional status).

3. The patient is being evaluated for suspected urosepsis, fever of unknown origin, or other systemic manifestations of infection but without a known source. Signs and symptoms used to define sepsis have been well-established.

4. A test-of cure is generally not indicated in an uncomplicated infection. However, it may be indicated if the patient is being evaluated for response to therapy and there is a complicating co-existing urinary abnormality including structural or functional abnormalities, calculi, foreign bodies, or ureteral/renal stents or there is clinical or laboratory evidence of failure to respond as described in Indications 1 and 2.

5. In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases (for example, prior to renal transplantation, manipulation or removal of kidney stones, or transurethral surgery of the bladder or prostate).

6. Urine culture may be indicated to detect occult infection in renal transplant recipients on immunosuppressive therapy.

Limitations

1. CPT 87086 or 87087 may be used one time per encounter. CPT 87086 and 87087 are not used concurrently.

2. Colony count restrictions on coverage of CPT 87088 do not apply as

they may be highly variable according to syndrome or other clinical circumstances (for example , antecedent therapy, collection time, degree of hydration).

3. CPT 87088, 87184, and 87186 may be used multiple times in association with or independent of 87086 or 87087, as urinary tract infections may be polymicrobial.

4. Testing for asymptomatic bacteriuria as part of a prenatal evaluation may be medically appropriate but is considered screening and therefore not covered by Medicare. The US Preventive Services Task Force has concluded that screening for asymptomatic bacteriuria outside of the narrow indication for pregnant women is generally not indicated. There are insufficient data to recommend screening in ambulatory elderly patients including those with diabetes. Testing may be clinically indicated on other grounds including likelihood of recurrence or potential adverse effects of antibiotics, but is considered screening in the absence of clinical or laboratory evidence of infection.

ICD–9–CM Codes Covered by Medicare Program

Code	Descriptor
003.1	Salmonella Septicemia
038.0–038.9	Septicemia
276.2	Acidosis
276.4	Metabolic acidosis/alkalosis
286.6	Defibrination syndrome/disseminated intravascular coagulation
288.0	Agranulocytosis/neutropenia
288.8	Other specified disease of white blood cells including leukemoid reaction/leukocytosis
306.53	Psychogenic dysuria
306.59	Other psychogenic genitourinary malfunction
518.82	Other pulmonary insufficiency, not elsewhere classified
570	Acute and subacute necrosis of liver
580.0–580.9	Acute glomerulonephritis
583.0–583.9	Nephritis and Nephropathy, not specified as acute or chronic
584.5	Acute renal failure, with lesion of tubular necrosis
584.9	Acute renal failure, unspecified
585	Chronic renal failure
586	Renal failure, unspecified
590.00–590.9	Infections of kidney/pyelonephritis acute and chronic
592.0–592.9	Calculus of kidney and ureter
593.0–593.9	Other disorders of kidney and ureter (cyst, stricture, obstruction, reflux, etc.)
594.0–594.9	Calculus of lower urinary tract
595.0–595.9	Cystitis
597.0	Urethritis, not sexually transmitted and urethral syndrome
597.80–597.89	Other urethritis
598.00–598.01	Urethral stricture due to infection
599.0	Urinary tract infection, site not specified
599.7	Hematuria
600	Hyperplasia of prostate
601.0–601.9	Inflammatory diseases of prostate
602.0–602.9	Other disorders of prostate (calculus, congestion, atrophy, etc.)
604.0–604.99	Orchitis and epididymitis
608.0–608.9	Other disorders of male genital organs (seminal vesiculitis, spermatocele, etc.)
614.0–614.9	Inflammatory disease of ovary, fallopian tube, pelvic cellular tissue, and peritoneum
615.0–615.9	Inflammatory disease of uterus, except cervix
616.0	Cervicitis and endocervicitis
616.10–616.11	Vaginitis and vulvovaginitis
616.2–616.9	Other inflammatory conditions of cervix, vagina and vulva
619.0–619.9	Fistula involving female genital tract
625.6	Stress incontinence, female
639.0	Genital tract and pelvic infection complicating abortion, ectopic or molar pregnancies
639.5	Shock complicating abortion, ectopic or molar pregnancies
646.60–.64	Infections of genitourinary tract in pregnancy
670.00–.04	Major puerperal infection
672.00–.04	Pyrexia of unknown origin during the puerperium
724.5	Backache, unspecified
780.2	Syncope and collapse
780.6	Fever (Hyperthermia)
780.79	Other malaise and fatigue
780.9	Other general symptoms (altered mental status, chills, generalized pains)
785.0	Tachycardia, unspecified
785.50–.59	Shock without mention of trauma
788.0–788.9	Symptoms involving urinary system (renal colic, dysuria, retention of urine, incontinence of urine, frequency, polyuria, nocturia, oliguria, anuria, other abnormality of urination, urethral discharge, extravasation of urine, other symptoms of urinary system)
789.00–789.09	Abdominal pain
789.60–789.69	Abdominal tenderness
790.7	Bacteremia
791.0–791.9	Nonspecific findings on examination of urine (proteinuria, chyluria, hemoglobinuria, myoglobinuria, biliuria, glycosuria, acetonuria, other cells and casts in urine, other nonspecific findings on examination of urine)

Code	Descriptor
799.3	Debility, unspecified (only for declining functional status)
939.0	Foreign body in genitourinary tract, bladder and urethra
939.3	Foreign body in genitourinary tract, penis
V44.50–V44.6	Artificial cystostomy or other artificial opening of urinary tract status
V55.5–V55.6	Attention to cystostomy or other artificial opening of urinary tract
V58.69	Long-term (current) use of other medications
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section has not been negotiated by the Negotiated Rulemaking Committee. It includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as notreasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Descriptor
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases

Code	Descriptor
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections.

Sources of Information

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Clarridge, JE, JR Johnson, and MT Pezzlo. 1998 (in press). Cumitech 2B: Laboratory Diagnosis of Urinary Tract Infections. AS Weissfeld (coor. ed.); ASM Press, Washington, DC.

Kunin, CM. 1994. Urinary tract infections in females. Clin. Infect. Dis. 18:1–12.

Sodeman, TM. 1995. A practical strategy for diagnosis of urinary tract infections. Clin. Lab. Med. 15:235–250.

Stamm WE, and TM Hooton. 1993. Management of urinary tract infections in adults. N. Engl. J. Med. 329:1328–1334.

United States Preventive Services Task Force (1996). Guidelines for screening for asymptomatic bacteriuria.

Lachs MS, Nachamkin I, Edelstein PH et al. 1992. Spectrum bias in the evaluation of diagnostic tests: lessons from the rapid dipstick test for urinary tract infection. Ann. Int. Med. 117:135–140.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS Codes'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43).

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52).

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44).

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'', ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. In the case of pre-operative examination (V72.84), the following codes may support medical necessity: 585, 586, 592.0–592.9, 594.0–594.9, 600, 602.0–602.9, 939.0, 939.3.

7. Specific coding guidelines:

a. Use CPT 87086 Culture, bacterial, urine; quantitative, colony count where a urine culture colony count is performed to determine the approximate number of bacteria present per milliliter of urine. The number of units of service is determined by the number of specimens.

b. Use CPT 87087 Culture, bacterial, urine; commercial kit where a commercial kit uses manufacturer defined media for isolation, presumptive identification, and quantitation of morphotypes present. The number of units of service is determined by the number of specimens.

c. Use CPT 87088 Culture, bacterial, urine; identification in addition to quantitative or commercial kit where identification of morphotypes recovered by quantitative culture or commercial kits and deemed to represent significant bacteriuria requires the use of additional testing, for example, biochemical test procedures on colonies. Identification based solely on visual observation of the primary media is usually not adequate to justify use of this code. The number of units of service is determined by the number of isolates.

d. Use CPT 87184 or 87186, Sensitivity studies where susceptibility testing of isolates deemed to be significant is performed concurrently with identification. The number of units of service is determined by the number of isolates. These codes are not exclusively used for urine cultures but are appropriate for isolates from other sources as well.

e. Appropriate combinations are as follows: CPT 87086 or 87087, 1 per specimen with 87088, 1 per isolate and 87184 or 87186 where appropriate.

f. Culture for other specific organism groups not ordinarily recovered by media used for aerobic urine culture may require use of additional CPT codes (for example, anaerobes from suprapubic samples).

g. Identification of isolates by non-routine, nonbiochemical methods may be coded appropriately (for example, immunologic identification of streptococci, nucleic acid techniques for identification of N. gonorrhoeae).

h. While infrequently used, sensitivity studies by methods other than CPT 87184 or 87186 are appropriate. CPT 87181, agar dilution method, each antibiotic or CPT 87188, macrotube dilution method, each antibiotic may be used. The number of units of service is the number of antibiotics multiplied by the number of unique isolates.

8. ICD–9–CM code 780.02, 780.9 or 799.3 should be used only in the situation of an elderly patient, immunocompromised patient or patient with neurologic disorder who presents without typical manifestations of a urinary tract infection but who presents with one of the following signs or symptoms, not otherwise explained by another co-existing condition: increasing debility; declining functional status; acute mental changes; changes in awareness; or hypothermia.

9. In cases of post renal-transplant urine culture used to detect clinically

significant occult infection in patients on long term immunosuppressive therapy, use code V58.69.

Documentation Requirements

Appropriate HCPCS/CPT code(s) must be used as described.

National Coverage Decision for: Human Immunodeficiency Virus Testing (Prognosis including monitoring)

Other Names/Abbreviations: HIV–1 or HIV–2 quantification or viral load

Description

HIV quantification is achieved through the use of a number of different assays which measure the amount of circulating viral RNA. Assays vary both in methods used to detect viral RNA as well as in ability to detect viral levels at lower limits. However, all employ some type of nucleic acid amplification technique to enhance sensitivity, and results are expressed as the HIV copy number.

Quantification assays of HIV plasma RNA are used prognostically to assess relative risk for disease progression and predict time to death, as well as to assess efficacy of antiretroviral therapies over time.

HIV quantification is often performed together with CD4+ T cell counts which provide information on extent of HIV induced immune system damage already incurred.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
7536	Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, quantification
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, quantification

Indications

1. A plasma HIV RNA baseline level may be medically necessary in any patient with confirmed HIV infection.

2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate or modify antiretroviral treatment regimens.

3. In clinical situations where the risk of HIV infection is significant and initiation of therapy is anticipated, a baseline HIV quantification may be performed. These situations include:

a. Persistence of borderline or equivocal serologic reactivity in an at-risk individual.

b. Signs and symptoms of acute retroviral syndrome characterized by fever, malaise, lymphadenopathy and rash in an at-risk individual.

Limitations

1. Viral quantification may be appropriate for prognostic use including baseline determination, periodic monitoring, and monitoring of response to therapy. Use as a diagnostic test method is not indicated.

2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis. For an accurate baseline, 2 specimens in a 2-week period are appropriate.

3. For prognosis including anti-retroviral therapy monitoring, regular, periodic measurements are appropriate. The frequency of viral load testing should be consistent with the most current Centers for Disease Control and Prevention guidelines for use of anti-retroviral agents in adults and adolescents or pediatrics.

4. Because differences in absolute HIV copy number are known to occur using different assays, plasma HIV RNA levels should be measured by the same analytical method. A change in assay method may necessitate re-establishment of a baseline.

5. Nucleic acid quantification techniques are representative of rapidly emerging and evolving new technologies. As such, users are advised to remain current on FDA-approval status.

ICD–9–CM Codes Covered by Medicare Program

Code	Descriptor
042	Human immunodeficiency virus [HIV] disease
079.53	Human immunodeficiency virus, type 2 [HIV–2]
647.60–.64	Other viral diseases complicating pregnancy (including HIV–I and II)
795.71	Nonspecific serologic evidence of human immunodeficiency virus [HIV]
V08	Asymptomatic human immunodeficiency virus [HIV] infection status

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. It includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. The documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not

reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Descriptor
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

CDC. 1998. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. MMWR 47 (RR–5).

CDC. 1998. Guidelines for the use of antiretroviral agents in pediatric HIV infection. MMWR 47 (RR–4).

CDC. 1998. Public Health Service Task Force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV–1 for maternal health and for reducing perinatal HIV–1 transmission in the United States. MMWR 47 (RR–2).

Carpenter, C.C., M.A. Fischi, S.M. Hammer, et al. 1998. Antiretroviral therapy for HIV infection in 1998. Updated recommendations of the international AIDS society-USA panel. .A.M.A. 280:78–86.

Saag, M.S., M. Holodniy, D.R. Kuritzkes, et al. 1996. HIV viral load markers in clinical practice. Nature Medicine 2(6): 625–629.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used.

(From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. Specific coding guidelines:

a. Temporary code G0100 has been superseded by code 87536 effective January 1, 1998.

b. CPT codes for quantification should not be used simultaneously with other nucleic acid detection codes for HIV–1 (that is, 87534, 87535) or HIV–2 (that is, 87537, 87538).

7. Codes 647.60–.64 should only be used for HIV infections complicating pregnancy.

Other Comments

Assessment of CD4+ T cell numbers is frequently performed in conjunction with viral load determination. When used in concert, the accuracy with which the risk for disease progression and death can be predicted is enhanced.

Medicare National Coverage Decision

For: Human Immunodeficiency Virus Testing (Diagnosis).

Other Names/Abbreviations: HIV, HIV–1, HIV–2, HIV1/2, HTLV III, Human T-cell lymphotrophic virus, AIDS, Acquired immune deficiency syndrome.

Description

Diagnosis of Human Immunodeficiency Virus (HIV) infection is primarily made through the use of serologic assays. These assays take one of two forms: antibody detection assays and specific HIV antigen (p24) procedures. The antibody assays are usually enzyme immunoassays (EIA) which are used to confirm exposure of an individual's immune system to specific viral antigens. These assays may be formatted to detect HIV–1, HIV–2, or HIV–1 and 2 simultaneously and to detect both IgM and IgG. When the initial EIA test is repeatedly positive or indeterminant, an alternative test is used to confirm the specificity of the antibodies to individual viral components. The most commonly used method is the Western Blot.

The HIV–1 core antigen (p24) test detects circulating viral antigen which may be found prior to the development of antibodies and may also be present in later stages of illness in the form of recurrent or persistent antigenemia. Its prognostic utility in HIV infection has been diminished as a result of development of sensitive viral RNA assays, and its primary use today is as a routine screening tool in potential blood donors.

In several unique situations, serologic testing alone may not reliably establish an HIV infection. This may occur because the antibody response (particularly the IgG response detected by Western Blot) has not yet developed (that is, acute retroviral syndrome), or is persistently equivocal because of inherent viral antigen variability. It is also an issue in perinatal HIV infection due to transplacental passage of maternal HIV antibody. In these situations, laboratory evidence of HIV in blood by culture, antigen assays, or proviral DNA or viral RNA assays, is required to establish a definitive determination of HIV infection.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
86689	Qualitative or semiquantitative immunoassays performed by multiple step methods; HTLV or HIV antibody, confirmatory test (for example, Western Blot)
86701	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–1
86702	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–2
86703	Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–1 and HIV–2, single assay
87390	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multiple step; HIV–1
87391	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multiple step; HIV–2
87534	Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, direct probe technique
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, direct probe technique HIV–1, amplified probe technique
87537	Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, direct probe technique
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, amplified probe technique

Indications

Diagnostic testing to establish HIV infection may be indicated when there is a strong clinical suspicion supported by one or more of the following clinical findings:

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.

2. The patient has another documented sexually transmitted disease which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.

3. The patient has documented acute or chronic hepatitis B or C infection that identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.

4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.

5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.

6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).

7. The patient has otherwise unexplained generalized signs and

symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).

8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia, pancytopenia, lymphopenia, or low CD4+ lymphocyte count).

9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash.

10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, needlesticks and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.

11. The patient is undergoing treatment for rape. (HIV testing is a part of the rape treatment protocol.) For a comprehensive tabulation of AIDS-defining and AIDS associated conditions, refer to information source document #5.

Limitations

1. HIV antibody testing in the United States is usually performed using HIV–1 or HIV–½ combination tests. HIV–2 testing is indicated if clinical circumstances suggest HIV–2 is likely (that is, compatible clinical findings and HIV–1 test negative). HIV–2 testing may also be indicated in areas of the country where there is greater prevalence of HIV–2 infections.

2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.

3. The HIV antigen tests currently have no defined diagnostic usage.

4. Direct viral RNA detection may be performed in those situations where serologic testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).

5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.

6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3–6 months.

7. Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV. However, in the absence of a documented AIDS defining or HIV associated disease, an HIV associated sign or symptom, or documented exposure to a known HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).

8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approval status for these tests.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
003.1	Salmonella septicemia
007.2	Coccidiosis (Isoporiasis)
007.4	Cryptosporidiosis
007.8	Other specified protozoal intestinal diseases
010.00–010.96	Primary tuberculous infection
011.00–011.96	Pulmonary tuberculosis
012.00–012.86	Other respiratory tuberculosis
013.00–013.96	Tuberculosis of meninges and central nervous system
014.00–014.86	Tuberculosis of intestines, peritoneum and mesenteric glands
015.00–015.96	Tuberculosis of bones and joints
016.00–016.96	Tuberculosis of genitourinary system
017.00–017.96	Tuberculosis of other organs
018.00–018.96	Miliary tuberculosis
027.0	Listeriosis
031.0–031.9	Diseases due to other mycobacteria
038.2	Pneumococcal septicemia
038.43	Septicemia (Pseudomonas)
039.0–.9	Actinomycotic infections (includes Nocardia)
041.7	Pseudomonas infection
042	HIV disease (Acute retroviral syndrome, AIDS-related complex)
046.3	Progressive multifocal leukoencephalopathy
049.0–049.9	Other non-arthropod-borne viral diseases of central nervous system
052.0–052.8	Chickenpox (with complication)
053.0–053.9	Herpes zoster
054.0–054.9	Herpes simplex
055.0–055.8	Measles (with complication)
070.20–070.23	Viral hepatitis B with hepatic coma
070.30–070.33	Viral hepatitis B without mention of hepatic coma
070.41	Acute or unspecified hepatitis C with hepatic coma
070.42	Hepatitis delta without mention of active hepatitis B disease with hepatic coma
070.44	Chronic hepatitis C with hepatic coma
070.49	Other specified viral hepatitis with hepatic coma
070.51	Acute or unspecified hepatitis C without hepatic coma
070.52	Hepatitis delta without mention of active hepatitis B disease without hepatic coma
070.54	Chronic hepatitis C without hepatic coma
070.59	Other specified viral hepatitis without hepatic coma

Code	Description
070.6	Unspecified viral hepatitis with hepatic coma
070.9	Unspecified viral hepatitis without hepatic coma
078.0	Molluscum contagiosum
078.10–078.19	Viral warts
078.3	Cat-scratch disease
078.5	Cytomegaloviral disease
078.88	Other specified diseases due to Chlamydiae
079.50	Retrovirus unspecified
079.51	HTLV–I
079.52	HTLV–II
079.53	HTLV–III
079.59	Other specified Retrovirus
079.88	Other specified chlamydial infection
079.98	Unspecified chlamydial infection
085.0–085.9	Leishmaniasis
088.0	Bartonellosis
090.0–090.9	Congenital syphilis
091.0–091.9	Early syphilis symptomatic
092.0–092.9	Early syphilis, latent
093.0–093.9	Cardiovascular syphilis
094.0–094.9	Neurosyphilis
095.0–095.9	Other forms of late syphilis, with symptoms
096	Late syphilis, latent
097.0–097.9	Other and unspecified syphilis
098.0–098.89	Gonococcal infections
099.0	Chancroid
099.1	Lymphogranuloma venereum
099.2	Granuloma inguinale
099.3	Reiter's disease
099.40–099.49	Other nongonococcal urethritis
099.50–099.59	Other venereal diseases due to Chlamydia trachomatis
099.8	Other specified venereal disease
099.9	Venereal disease unspecified
110.1	Dermatophytosis of nail
111.0	Pityriasis versicolor
112.0–112.9	Candidiasis
114.0–114.9	Coccidioidomycosis
115.00–115.99	Histoplasmosis
116.0–116.2	Blastomycotic infection
117.3	Aspergillosis
117.5	Cryptococcosis
118	Opportunistic mycoses
127.2	Strongyloidiasis
130.0–130.9	Toxoplasmosis
131.01	Trichomonal vulvovaginitis
132.2	Phthirus pubis
133.0	Scabies
136.2	Specific infections by free living amebae
136.3	Pneumocystosis
136.8	Other specified infectious and parasitic disease (for example, microsporidiosis)
176.0–176.9	Kaposi's sarcoma
180.0–180.9	Malignant neoplasm of cervix uteri
200.20–200.28	Burkitt's tumor or lymphoma
200.80–200.88	Lymphosarcoma, other named variants
201.00–201.98	Hodgkin's disease
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.9	Unspecified protein-calorie malnutrition
280.0–280.9	Iron deficiency anemias
285.9	Anemia, unspecified
287.3	Primary thrombocytopenia
288.0	Agranulocytosis
288.8	Other specified disease of white blood cells
294.8	Other specified organic brain syndromes (chronic)
310.1	Organic personality syndrome
322.2	Chronic meningitis
336.9	Unspecified disease of spinal cord
348.3	Encephalopathy unspecified
354.0–354.9	Mononeuritis of upper limbs and mononeuritis multiplex
356.8	Other specified idiopathic peripheral neuropathy
363.20	Chorioretinitis, unspecified
425.4	Other primary cardiomyopathies
473.0–473.9	Chronic sinusitis
481.0–482.9.1	Pneumococcal pneumonia

Code	Description
484.1	Pneumonia in cytomegalic inclusion disease
486	Pneumonia, organism unspecified
512.8	Other spontaneous pneumothorax
516.8	Other specified alveolar and parietoalveolar pneumonopathies
528.2	Oral aphthae
528.6	Leukoplakia of oral mucosa
530.2	Ulcer of esophagus
583.9	Nephropathy with unspecified pathological lesion in kidney
588.8	Other specified disorders resulting from impaired renal function
647.60–647.64	Other viral diseases complicating pregnancy (use for HIV I and II)
682.0–682.9	Other cellulitis and abscess
690.10–690.18	Seborrheic dermatitis
696.1	Other psoriasis
698.3	Lichenification and lichen simplex chronicus
704.8	Other specified diseases of hair and hair follicles
706.0–706.9	Diseases of sebaceous glands
780.6	Fever
780.79	Other malaise and fatigue
783.2	Abnormal loss of weight
783.4	Lack of expected normal physiological development
785.6	Enlargement of lymph nodes
786.00	Respiratory abnormality, unspecified
786.05	Shortness of breath
786.2	Cough
786.3	Hemoptysis
786.4	Abnormal sputum
787.91	Diarrhea
795.71	Nonspecific serologic evidence of human immunodefiency virus
799.4	Wasting disease
V01.7	Contact with or exposure to communicable diseases, other viral diseases
V71.5	Rape

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases

Code	Description
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

CDC, 1993. Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 41 (No. RR17).

CDC, 1994. Revised classification system for human immunodeficiency virus infection in children less than 13 years of age.

CDC, 1998. Guidelines for treatment of sexually transmitted diseases. MMWR 47 (RR1):11–17.

Piatak, M., M.S. Saag, L.C. Yang, et al. 1993. High levels of HIV–1 in plasma during all stages of infection determined by competitive PCR. Science 259:1749–1754.

Rhame, R.S. 1994. Acquired immunodeficiency syndrome, p. 628–652. *In Infectious Diseases;* P.D. Hoeprich, M.C. Jordan, and A.R. Ronald (J.B. Lippincott Co., Philadelphia).

Vasudevachari, M.D., R.T. Davey, Jr., J.A. Metcalf, and H.C. Lane. 1997. Principles and procedures of human immunodeficiency virus serodiagnosis. *In Manual of Clinical Laboratory Immunology* (Fifth ed.); N.R. Rose, E.C. de Macario, J.D. Folds, H.C. Lane, and R.M. Nakamura (ASM Press, Washington, DC).

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. Specific coding guidelines:

a. CPT 86701 or 86703 is performed initially. CPT 86702 is performed when 86701 is negative and clinical suspicion of HIV–2 exists.

b. CPT 86689 is performed only on samples repeatedly positive by 86701, 86702, or 86703.

c. CPT 87534 or 87535 is used to detect HIV–1 RNA where indicated. CPT 87537 or 87538 is used to detect HIV–2 RNA where indicated.

Documentation Requirements

Appropriate HCPCS/CPT codes must be used as described.

Medicare National Coverage Decision:

Blood Counts

Other Names/Abbreviations: CBC

Description

Blood counts are used to evaluate and diagnose diseases relating to abnormalities of the blood or bone marrow. These include primary disorders such as anemia, leukemia, polycythemia, thrombocytosis and thrombocytopenia. Many other conditions secondarily affect the blood or bone marrow, including reaction to inflammation and infections, coagulopathies, neoplasms and exposure to toxic substances. Many treatments and therapies affect the blood or bone marrow, and blood counts may be used to monitor treatment effects.

The complete blood count (CBC) includes a hemogram and differential white blood count (WBC). The hemogram includes enumeration of red blood cells, white blood cells, and platelets, as well as the determination of hemoglobin, hematocrit, and indices.

The symptoms of hematological disorders are often nonspecific, and are commonly encountered in patients who may or may not prove to have a disorder of the blood or bone marrow. Furthermore, many medical conditions that are not primarily due to abnormalities of blood or bone marrow may have hematological manifestations that result from the disease or its treatment. As a result, the CBC is one of the most commonly indicated laboratory tests.

In patients with possible hematological abnormalities, it may be necessary to determine the hemoglobin and hematocrit, to calculate the red cell indices, and to measure the concentration of white blood cells and platelets. These measurements are usually performed on a multichannel analyzer that measures all of the parameters on every sample. Therefore, laboratory assessments routinely include these measurements.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
85007	Blood count; manual differential WBC count (includes RBC morphology and platelet estimation)
85008	Blood counts, manual blood smear examination without differential parameters
85013	Blood counts, Spun microhematocrit
85014	Blood counts, Other than spun hematocrit
85018	Blood counts, Hemoglobin
85021	Blood counts, Hemogram, automated (RBC, WBC, Hgb, Hct, and indices only)
85022	Blood counts, Hemogram, automated, and manual differential WBC count (CBC)
85023	Blood counts, Hemogram and platelet count, automated, and manual differential WBC count (CBC)
85024	Blood counts, Hemogram and platelet count, automated, and automated partial differential WBC count (CBC)
85025	Hemogram and platelet count, automated and automated complete differential WBC count (CBC)
85027	Blood counts, Hemogram and platelet count, automated
85031	Blood count; hemogram, manual, complete CBC (RBC, Hgb, Hct, differential and indices
85048	Blood counts, White blood cell (WBC)
85590	Platelet; manual count
85595	Platelet, automated count

Indications

Indications for a CBC or hemogram include red cell, platelet, and white cell disorders. Examples of these indications are enumerated individually below.

1. Indications for a CBC generally include the evaluation of bone marrow dysfunction as a result of neoplasms, therapeutic agents, exposure to toxic substances, or pregnancy. The CBC is also useful in assessing peripheral destruction of blood cells, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic, or lymphoproliferative processes, and immune disorders.

2. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorder (e.g., pallor, weakness, fatigue, weight loss, bleeding, acute injury associated with blood loss or suspected blood loss, abnormal menstrual bleeding, hematuria, hematemesis, hematochezia, positive fecal occult blood test, malnutrition, vitamin deficiency, malabsorption, neuropathy, known malignancy, presence of acute or chronic disease that may have associated anemia, coagulation or hemostatic disorders, postural dizziness, syncope, abdominal pain, change in bowel habits, chronic marrow hypoplasia or decreased RBC production, tachycardia, systolic heart murmur, congestive heart failure, dyspnea, angina, nailbed deformities, growth retardation, jaundice, hepatomegaly, splenomegaly, lymphadenopathy, ulcers on the lower extremities).

3. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with polycythemia (for example, fever, chills, ruddy skin, conjunctival redness, cough, wheezing, cyanosis, clubbing of the fingers, orthopnea, heart murmur, headache, vague cognitive changes including memory changes, sleep apnea, weakness, pruritus, dizziness, excessive sweating, visual symptoms, weight loss, massive obesity, gastrointestinal bleeding, paresthesias, dyspnea, joint symptoms, epigastric distress, pain and erythema of the fingers or toes, venous or arterial thrombosis, thromboembolism, myocardial infarction, stroke, transient ischemic attacks, congenital heart disease, chronic obstructive pulmonary disease, increased erythropoetin production associated with neoplastic, renal or hepatic disorders, androgen or diuretic use, splenomegaly, hepatomegaly, diastolic hypertension.)

4. Specific indications for CBC with differential count related to the WBC include signs, symptoms, test results, illness, or disease associated with leukemia, infections or inflammatory processes, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic or lymphoproliferative disorder, use of drugs that may cause leukopenia, and immune disorders (e.g., fever, chills, sweats, shock, fatigue, malaise, tachycardia, tachypnea, heart

murmur, seizures, alterations of consciousness, meningismus, pain such as headache, abdominal pain, arthralgia, odynophagia, or dysuria, redness or swelling of skin, soft tissue bone, or joint, ulcers of the skin or mucous membranes, gangrene, mucous membrane discharge, bleeding, thrombosis, respiratory failure, pulmonary infiltrate, jaundice, diarrhea, vomiting, hepatomegaly, splenomegaly, lymphadenopathy, opportunistic infection such as oral candidiasis.)

5. Specific indications for CBC related to the platelet count include signs, symptoms, test results, illness, or disease associated with increased or decreased platelet production and destruction, or platelet dysfunction (e.g., gastrointestinal bleeding, genitourinary tract bleeding, bilateral epistaxis, thrombosis, ecchymosis, purpura, jaundice, petechiae, fever, heparin therapy, suspected DIC, shock, pre-eclampsia, neonate with maternal ITP, massive transfusion, recent platelet transfusion, cardiopulmonary bypass, hemolytic uremic syndrome, renal diseases, lymphadenopathy, hepatomegaly, splenomegaly, hypersplenism, neurologic abnormalities, viral or other infection, myeloproliferative, myelodysplastic, or lymphoproliferative disorder, thrombosis, exposure to toxic agents, excessive alcohol ingestion, autoimmune disorders (SLE, RA and other).

6. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include, in addition to those already listed, thalassemia, suspected hemoglobinopathy, lead poisoning, arsenic poisoning, and spherocytosis.

7. Specific indications for CBC with differential count related to the WBC include, in addition to those already listed, storage diseases/ mucopolysaccharidoses, and use of drugs that cause leukocytosis such as G–CSF or GM–CSF.

8. Specific indications for CBC related to platelet count include, in addition to those already listed, May-Hegglin syndrome and Wiskott-Aldrich syndrome.

Limitations

1. Testing of patients who are asymptomatic, or who do not have a condition that could be expected to result in a hematological abnormality, is screening and is not a covered service.

2. In some circumstances it may be appropriate to perform only a hemoglobin or hematocrit to assess the oxygen carrying capacity of the blood. When the ordering provider requests only a hemoglobin or hematocrit, the remaining components of the CBC are not covered.

3. When a blood count is performed for an end-stage renal disease (ESRD) patient, and is billed outside the ESRD rate, documentation of the medical necessity for the blood count must be submitted with the claim.

4. In some patients presenting with certain signs, symptoms or diseases, a single CBC may be appropriate. Repeat testing may not be indicated unless abnormal results are found, or unless there is a change in clinical condition. If repeat testing is performed, a more descriptive diagnosis code (e.g., anemia) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a continued risk for the development of hematologic abnormality.

ICD–9–CM Codes Covered by Medicare Program

Any ICD–9–CM code not listed in either of the ICD–9–CM code sections below.

Reasons for Denial

[**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.]

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
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- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

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V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases

Code	Description
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Code	Description
078.10–078.19	Viral warts
210.0–210.9	Benign neoplasm of lip, oral cavity, and pharynx
214.0	Lipoma, skin and subcutaneous tissue of face
216.0–216.9	Benign neoplasm of skin
217	Benign neoplasm of breast
222.0–222.9	Benign neoplasm of male genital organs
224.0	Benign neoplasm of eye
230.0	Carcinoma in situ of lip, oral cavity and pharynx
232.0–232.9	Carcinoma in situ of skin
300.00–300.09	Neurotic disorders
301.0–301.9	Personality disorders
302.0–302.9	Sexual deviations and disorders
307.0	Stammering and stuttering
307.20–307.23	Tics
307.3	Stereotyped repetitive movements
307.80–307.89	Psychalgia
312.00–312.9	Disturbance of conduct, not elsewhere classified
313.0–313.9	Disturbance of emotions specific to childhood and adolescence
314.00–314.9	Hyperkinetic syndrome of childhood
363.30–363.35	Chorioretinal scars
363.40–363.43	Choroidal degeneration
363.50–363.57	Hereditary choroidal dystrophies
363.70–363.9	Choroidal detachment
366.00–366.9	Cataract
367.0–367.9	Disorders of refraction and accommodation
371.00–371.9	Corneal opacity and other disorders of cornea
373.00–373.9	Inflammation of eyelids
375.00–375.9	Disorders of lacrimal system
376.21–376.9	Disorders of the orbit, *except 376.3 Other exophthalmic conditions*
377.10–377.16	Optic atrophy
377.21–377.24	Other disorders of optic disc
384.20–384.25	Perforation of tympanic membrane
384.81–384.82	Other specified disorders of tympanic membrane
385.00–385.90	Other disorders of middle ear and mastoid
387.0–387.9	Otosclerosis
388.00–388.5	Other disorders of ear
389.00–389.9	Hearing loss
440.0–440.1	Atherosclerosis of aorta and renal artery
443.8–443.9	Peripheral vascular disease
448.1	Capillary nevus, non neoplastic
457.0	Postmastectomy lymphedema syndrome
470	Deviated nasal septum
471.0–471.9	Nasal polyps
478.0	Hypertrophy of nasal turbinates

Code	Description
478.4	Polyp of vocal cord or larynx
520.0–520.9	Disorders of tooth development and eruption
521.0–521.9	Diseases of hard tissues of teeth
524.00–524.9	Dentofacial anomalies, including malocclusion
525.0–525.9	Other diseases and conditions of teeth and supporting structures
526.0–526.3	Diseases of the jaws
527.6–527.9	Diseases of the salivary glands
575.6	Cholesterolosis of gallbladder
600	Hyperplasia of prostate
603.0	Encysted hydrocele
603.8	Other specified types of hydrocele
603.9	Hydrocele, unspecified
605	Redundant prepuce and phimosis
606.0–606.1	Infertility, male
608.1	Spermatocoele
608.3	Atrophy of testis
610.0–610.9	Benign mammary dysplasia
611.1–611.6	Other disorders of breast
611.9	Unspecified breast disorder
616.2	Cyst of Bartholin's gland
618.0–618.9	Genital prolapse
620.0–620.3	Noninflammatory disorders of ovary, fallopian tube, and broad ligament
621.6–621.7	Malposition or inversion of uterus
627.2–627.9	Menopausal and post menopausal disorders
628.0–628.9	Infertility, female
676.00–676.94	Other disorders of breast associated with childbirth and disorders of lactation
691.0–691.8	Atopic dermatitis and related disorders
692.0–692.9	Contact dermatitis and other eczema
700	Corns and callosities
701.0–701.9	Other hypertrophic and atrophic conditions of skin
702.0–702.8	Other dermatoses
703.9	Unspecified disease of nail
706.0–706.9	Diseases of sebaceous glands
709.00–709.4	Other disorders of skin and subcutaneous tissue
715.00–715.98	Osteoarthrosis
716.00–716.99	Other and unspecified arthropathies
718.00–718.99	Other derangement of joint
726.0–726.91	Peripheral esthesiopathies and allied syndromes
727.00–727.9	Other disorders of synovium, tendon, and bursa
728.10–728.85	Disorders of muscle ligament and fascia
732.0–732.9	Osteochondropathies
733.00–733.09	Osteoporosis
734	Flat foot
735.0–735.9	Acquired deformities of toe
736.00–736.9	Other acquired deformities of limb
737.0–737.9	Curvature of spine
738.0–738.9	Other acquired deformity
739.0–739.9	Nonallopathic lesions, not elsewhere classified
830.0–839.9	Dislocations
840.0–848.9	Sprains and strains
905.0–909.9	Late effects of musculoskeletal and connective tissue injuries
910.0–919.9	Superficial injuries
930.0–932	Foreign body on external eye, in ear, in nose
955.0–957.9	Injury to peripheral nerve
V03.0–V06.9	Need for prophylactic vaccination
V11.0–V11.9	Personal history of mental disorder
V14.0–V14.8	Personal history of allergy to medicinal agents
V16.0	Family history of malignant neoplasm, gastrointestinal tract
V16.3	Family history of malignant neoplasm, breast
V21.0–V21.9	Constitutional states in development
V25.01–V25.9	Encounter for contraceptive management
V26.0–V26.9	Procreative management
V40.0–V40.9	Mental and behavioral problems
V41.0–V41.9	Problems with special senses and other special functions
V43.0–V43.1	Organ or tissue replaced by other means, eye globe or lens
V44.0–V44.9	Artificial opening status
V45.00–V45.89	Other post surgical states
V48.0–V48.9	Problems with head, neck, and trunk
V49.0–V49.9	Problems with limbs
V51	Aftercare involving the use of plastic surgery
V52.0–V52.9	Fitting and adjustment of prosthetic device and implant
V53.01–V53.09	Fitting and adjustment of devices related to nervous system and special senses
V53.1	Fitting and adjustment of spectacles and contact lenses
V53.31–V53.39	Fitting and adjustment of cardiac device

Code	Description
V53.4	Fitting and adjustment of orthodontic devices
V53.5	Fitting and adjustment of other intestinal appliance
V53.6	Fitting and adjustment of urinary devices
V53.7	Fitting and adjustment of orthopedic devices
V53.8	Fitting and adjustment of wheelchair
V53.9	Fitting and adjustment of other and unspecified device
V54.0–V54.9	Other orthopedic aftercare
V55.0–V55.9	Attention to artificial openings
V57.0–V57.9	Care involving use of rehabilitation procedures
V58.5	Orthodontics
V59.0–V59.9	Donors
V61.0–V61.9	Other family circumstances
V62.2–V62.9	Other psychosocial circumstances
V65.2	Person feigning illness
V65.3	Dietary surveillance and counseling
V65.40–V65.49	Other counseling, not elsewhere classified
V65.5	Person with feared complaint in whom no diagnosis was made
V65.8	Other reasons for seeking consultation
V65.9	Unspecified reason for consultation
V66.0–V66.9	Convalescence and palliative care
V67.3	Follow-up examination following psychotherapy
V67.4	Follow-up examination following treatment of healed fracture
V69.3	Problems related to lifestyle, gambling and betting
V71.01–V71.09	Observation and evaluation for suspected conditions not found, mental
V72.0–V72.2	Special investigations, examination of eyes and vision, ears and hearing, dental
V72.4–V72.7	Special investigations, radiologic exam, laboratory exam, diagnostic skin and sensitization tests
V72.9	Special investigation, unspecified
V76.10–V76.19	Special screening for malignant neoplasms, breast
V76.2	Special screening for malignant neoplasms, cervix

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Cecil Textbook of Medicine, Bennett, et al., 20th edition, Philadelphia: W.B. Saunders, 1996.

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Partial Thromboplastin Time

Other Names/Abbreviations: PTT

Description

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The partial thromboplastin time (PTT), prothrombin time (PT), thrombin time (TT), or a quantitative fibrinogen determination. The partial thromboplastin time (PTT) test is an in vitro laboratory test used to assess the intrinsic coagulation pathway and monitor heparin therapy.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
85730	Thromboplastin time, partial (PTT); plasma or whole blood

Indications

1. The PTT is most commonly used to quantitate the effect of therapeutic unfractionated heparin and to regulate its dosing. Except during transitions between heparin and warfarin therapy, in general both the PTT and PT are not necessary together to assess the effect of anticoagulation therapy. PT and PTT must be justified separately. (See ''Limitations'' section for further discussion.)

2. A PTT may be used to assess patients with signs or symptoms of hemorrhage or thrombosis. For example:

abnormal bleeding, hemorrhage or hematoma petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation swollen extremity with or without prior trauma

3. A PTT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of hemorrhage or thrombosis that is related to the intrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example:

dysfibrinogenemia
afibrinogenemia (complete)
acute or chronic liver dysfunction or failure, including
Wilson's disease
hemophilia
liver disease and failure
infectious processes
bleeding disorders
disseminated intravascular coagulation
lupus erythematosus or other conditions associated with circulating inhibitors, e.g., Factor VIII Inhibitor, lupus-like anticoagulant, etc.
sepsis
von Willebrand's disease
arterial and venous thrombosis, including the evaluation of hypercoagulable states
clinical conditions associated with nephrosis or renal failure
other acquired and congenital coagulopathies as well as thrombotic states.

4. A PTT may be used to assess the risk of thrombosis or hemorrhage in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. An example is as follows:

evaluation prior to invasive procedures or operations of patients with personal or family history of bleeding or who are on heparin therapy

Limitations

1. The PTT is not useful in monitoring the effects of warfarin on a patient's coagulation routinely. However, a PTT may be ordered on a patient being treated with warfarin as heparin therapy is being discontinued. (See coding guidelines for instructions on the use of code V58.61 in this situation.) A PTT may also be indicated when the PT is markedly prolonged due to warfarin toxicity.

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of heparin.

3. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy.

Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
02.0–002.9	Typhoid and paratyphoid
03.0–003.9	Other Salmonella infections
038.9	Unspecified Septicemia
042	Human immunodeficiency virus (HIV) disease
060.0–060.9	Yellow fever
065.0–065.9	Arthopod borne hemorrhagic fever
070.0–070.9	Viral Hepatitis
075	Infectious mononucleosis
078.6	Hemorrhagic nephrosonephritis
078.7	Arenaviral hemorrhagic fever
120.0	Schistosomiasis haematobium
121.1	Clonorchiasis
121.3	Fascioliasis
124	Trichinosis
135	Sarcoidosis
155.0–155.2	Malignant neoplasm of liver and intrahepatic bile ducts
197.7	Malignant neoplasm of liver, specified as secondary
238.4	Polycythemia vera
238.7	Other lymphatic and hemapoietic tissues
239.9	Neoplasm of unspecified nature, site unspecified
246.3	Hemorrhage and infarction of thyroid
250.40–250.43	Diabetic with renal manifestations
269.0	Deficiency of Vitamin K
273.0–273.9	Disorders of plasma protein metabolism
273.2	Other paraproteinemias
275.0–275.9	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism

Code	Description
277.3	Amyloidosis
285.1	Acute posthemorrhagic anemia
286.0	Congenital factor VIII disorder—Hemophilia A
286.1	Congenital factor IX disorder—Hemophilia B
286.2–286.3	Other congenital factor deficiencies
286.4	von Willebrand's disease
286.5	Hemorrhagic disorder due to circulating anticoagulants
286.6	Defibrination syndrome
286.7	Acquired coagulation factor deficiency
286.8–286.9	Other and unspecified coagulation defects
287.0–287.9	Purpura and other hemorrhagic conditions
289.0	Polycythemia, secondary
325	Phlebitis and thrombophlebitis of intracranial ventricles sinuses
360.43	Hemophthalmos, except current injury
362.30–362.37	Retinal vasclar occlusion
362.34	Amaurosis fugax
362.43	Hemorrhagic detachmentof retinal pigment epithelium
362.81	Retinal hemorrhage
363.6	Choroidal hemorrhage
363.72	Choroidal detachment
368.9	Unspecified Visual Disturbances
372.72	Conjunctive hemorrhage
374.81	Hemorrhage of eyelid
376.32	Orbital hemorrhage
377.42	Hemorrhage in optic nerve sheaths
379.23	Vitreous hemorrhage
380.31	Hematoma of auricle or pinna
403.01, 403.11, 403.91	Hypertensive Renal Disease with renal failure
404.02, 404.12, 404.92	Hypertensive Heart and Renal Disease with renal failure
410.0–410.9	Acute myocardial infarction
423.0	Hemopericardium
427.31	Atrial fibrillation
427.9	Cardiac dysrhythmias, unspecified
428.0	Congestive heart failure
429.79	Mural thrombus
430–432.9	Cerebral hemorrhage
433.00–433.91	Occlusion and stenosis of precerebral arteries
434.00–434.91	Occlusion of cerebral arteries
435.9	Focal neurologic deficit
444.0–444.9	Arterial embolism and thrombosis
446.6	Thrombotic microangiopathy
447.2	Rupture of artery
448.0	Hereditary Hemorrhagic telangiectasia
451.0–451.9	Phlebitis and thrombophlebitis
453.0–453.9	Other Venous emboli and thrombosis
456.0	Esophageal varices with bleeding
456.1	Esophageal varices without bleeding
456.8	Varices of other sites
459.89	Ecchymosis
530.7	Gastroesophageal laceration—hemorrhage syndrome
530.82	Esophgael hemorrhage
531.00–535.61	Gastric-Duodenal ulcer disease
537.83	Angiodysplasia of stomach and duodenum with hemorrhage
556.0–557.9	Hemorrhagic bowel disease
562.02–562.03	Diverticulosis of small intestine with hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon without hemorrhage
568.81	Hemoperitoneum (nontraumatic)
569.3	Hemorrhage of rectum and anus
570	Acute and subacute necrosis of liver
571.0–573.9	Liver disease (in place of specific codes listed)
576.0–576.9	Biliary tract disorders
577.0	Acute pancreatitis
578.0–578.9	Gastrointestinal Hemorrhage
579.0–579.9	Malabsorption
581.0–581.9	Nephrotic Syndrome
583.9	Nephritis, with unspecified pathological lesion in kidney
584.5–584.9	Acute Renal Failure
585	Chronic Renal Failure
586	Renal failure
593.81–593.89	Other disorders of kidney and ureter, with hemorrhage
596.7	Hemorrhage into bladder wall
596.8	Other disorders of bladder, with hemorrhage
599.7	Hematuria

Code	Description
607.82	Penile hemorrhage
608.83	Vascular disorders of male genital organs
611.8	Hematoma of breast
620.7	Hemorrhage of broad ligament
621.4	Hematometra
622.8	Other specified disorders of cervix, with hemorrhage
623.6	Vaginal hematoma
623.8	Other specified diseases of the vagina, with hemorrhage
624.5	Hematoma of vulva
626.6	Metrorrhagia
626.7	Postcoital bleeding
627.0	Premenopausal bleeding
627.1	Postmenopausal bleeding
629.0	Hematocele female not elsewhere classified
632	Missed abortion
634.00–634.92	Spontaneous abortion
635.10–635.12	Legally induced abortion, complicated by delayed or excessive hemorrhage
636.10–636.12	Illegally induced abortion, complicated by delayed or excessive hemorrhage
637.10–637.12	Abortion unspecified, complicated by delayed or excessive hemorrhage
638.1	Failed attempt abortion, complicated by delayed or excessive hemorrhage
639.1	Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies
639.6	Complications following abortion and ectopic and molar pregnancies, embolism
640.00–640.93	Hemorrhage in early pregnancy
641.00–641.93	Antepartum hemorrhage
642.00–642.94	Hypertension complicating pregnancy, childbirth, and the puerperium
646.70–646.73	Liver disorders in pregnancy
656.00–656.03	Fetal maternal hemorrhage
658.40–658.43	Infection of amniotic cavity
666.00–666.34	Postpartum hemorrhage
671.20–671.54	Phlebitis in pregnancy
673.00–673.84	Obstetrical pulmonary embolus
674.30–674.34	Other complications of surgical wounds, with hemorrhage
710.0	Systemic Lupus erythematosus
713.2	Arthropathy associated with hematologic disorders (note: may not be used without indicating associated condition first)
713.6	Arthropathy associated with Henoch Schoenlein (note: may not be used without indicating associated condition first)
719.10–719.19	Hemarthrosis
729.5	Leg pain/calf pain
733.1	Pathologic fracture associated with fat embolism
762.1	Other forms of placental separation with hemorrhage (affecting newborn code do not assign to mother's record)
764.90–764.99	Fetal intrauterine growth retardation
767.0–767.1	Subdural and cerebral hemorrhage
767.8	Other specified birth trauma, with hemorrhage
770.3	Fetal and newborn pulmonary hemorrhage
772.0–772.9	Fetal and neonatal hemorrhage
774.0–772.7	Other perinatal jaundice
776.0–776.9	Hemorrhagic disease of the newborn
780.2	Syncope
782.4	Jaundice, unspecified, not of newborn
782.7	Spontaneous ecchymoses Petechiae
784.7	Epistaxis
784.8	Hemorrhage from throat
785.4	Gangrene
785.50	Shock
786.05	Shortness of breath
786.3	Hemoptysis
786.50	Chest pain, unspecified
786.59	Chest pain
789.00–789.09	Abdominal pain
790.92	Abnormal coagulation profile
800.00–800.99	Fracture of vault of skull
801.00–801.99	Fracture of base of skull
802.20–802.9	Fracture of face bones
803.00–803.99	Other fracture, skull
804.00–804.99	Multiple fractures, skull
805.00–806.9	Fracture, vertebral column
807.00–807.09	Fractures of rib(s), closed
807.10–807.19	Fracture of rib(s), open
808.8–808.9	Fracture of pelvis
809.0–809.1	Fracture of trunk
810.00–810.13	Fracture of clavicle
811.00–811.19	Fracture of scapula

Code	Description
812.00–812.59	Fracture of humerus
813.10–813.18	Fracture of radius and ulna, upper end, open
813.30–813.38	Fracture of radius and ulna, shaft, open
813.50–813.58	Fracture of radius and ulna, lower end, open
813.90–813.98	Fracture of radius and ulna, unspecified part, open
819.0–819.1	Multiple fractures
820.00–821.39	Femur
823.00–823.92	Tibia and fibula
827.0–829.1	Other multiple lower limb
852.00–853.19	Subarachnoid subdural, and extradural hemorrhage, following injury, Other and specified intracranial hemorrhage following injury
860.0–860.5	Traumatic pneumothorax and hemothorax
861.00–861.32	Injury to heart and lung
862.0–862.9	Injury to other and unspecified intrathoracic organs
863.0–863.9	Injury to gastrointestinal tract
864.00–863.19	Injury to liver
865.00–863.19	Injury to spleen
866.00–866.13	Injury to kidney
867.0–867.9	Injury to pelvic organs
868.00–868.19	Injury to other intra-abdominal organs
869.0–869.1	Internal injury to unspecified or ill defined organs
900.00–900.9	Injury to blood vessels of head and neck
901.0–901.9	Injury to blood vessels of the thorax
902.0–902.9	Injury to blood vessels of the abdomen and pelvis
903.00–903.9	Injury to blood vessels of upper extremity
904.0–904.9	Injury to blood vessels of lower extremity and unspecified sites
920—924.9	Contusion with intact skin surface
925.1–929.9	Crushing injury
958.2	Secondary and recurrent hemorrhage
959.9	Injury, unspecified site
964.2	Poisoning by anticoagulants
964.5	Poisoning by anticoagulant antagonists
964.7	Poisoning by natural blood and blood products
980.0	Toxic effects of alcohol
989.5	Snake venom
995.2	Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered)
996.7	Other complications of internal prosthetic device
997.02	Iatrogenic cerbrovascular infarction or hemorrhage
998.11	Hemorrhage or hematoma complicating a procedure
999.2	Other vascular complications of medical care
V12.3	Personal history of diseases of blood and blood forming organs
V58.2	Admission for Transfusion of blood products
V58.61	Long term (current use) of anticoagulants
V72.81	Pre-operative cardiovascular examination
V72.83	Other specified pre-operative examination
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic eoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

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1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the

condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. When patients are being converted from heparin therapy to warfarin therapy, use code V58.61 to document the medical necessity of the PTT.

7. When coding for Disseminated Intravascular Coagulation (DIC), use 286.6 or code for the signs and symptoms clinically indicating DIC.

8. If a specific condition is known and is the reason for a pre-operative test, submit the clinical text description or ICD–9–CM code describing the condition with the order/referral. If a specific condition or disease is not known, and the pre-operative test is for pre-operative clearance only, assign code V72.84.

9. Assign codes 289.8–other specified disease of blood and blood-forming organs only when a specific disease exists and is indexed to 289.8, (for example, myelofibrosis). Do not assign code 289.8 to report a patient on long term use of anticoagulant therapy (for example, to report a PTT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PTT checks or re-checks. (Reference AHA's Coding Clinic, March–April, pg 12—1987, 2nd quarter pg 8—1989)

Medicare National Coverage Decision for Prothrombin Time Other Names/Abbreviations: PT

Description

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: the partial thromboplastin time (PTT), prothrombin time (PT), thrombin time (TT), or a quantitative fibrinogen determination. The prothrombin time (PT) test is one in-vitro laboratory test used to assess coagulation. While the PTT assesses the intrinsic limb of the coagulation system, the PT assesses the extrinsic or tissue factor dependent pathway. Both tests also evaluate the common coagulation pathway involving all the reactions that occur after the activation of factor X. Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production or increased consumption of coagulation factors. The PT/INR is most commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors. A prothrombin time is expressed in seconds and/or as an international normalized ratio (INR). The INR is the PT ratio that would result if the WHO reference thromboplastin had been used in performing the test.

Current medical information does not clarify the role of laboratory PT testing in patients who are self monitoring. Therefore, the indications for testing apply regardless of whether or not the patient is also PT self-testing.

HCPCS Codes (Alpha numeric CPT © AMA)

Code	Descriptor
85610	Prothrombin Time

Indications

1. A PT may be used to assess patients taking warfarin. The prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.

2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example:

- Swollen extremity with or without prior trauma
- Unexplained bruising
- Abnormal bleeding, hemorrhage or hematoma
- Petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation

3. A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example:

- Dysfibrinogenemia
- Afibrinogenemia (complete)
- Acute or chronic liver dysfunction or failure, including
- Wilson's disease and Hemochromatosis
- Disseminated intravascular coagulation (DIC)
- Congenital and acquired deficiencies of factors II, V, VII, X;
- Vitamin K deficiency
- Lupus erythematosus
- Hypercoagulable state
- Paraproteinemia
- Lymphoma
- Amyloidosis
- Acute and chronic leukemias
- Plasma cell dyscrasia
- HIV infection
- Malignant neoplasms
- Hemorrhagic fever
- Salicylate poisoning
- Obstructive jaundice
- Intestinal fistula
- Malabsorption syndrome
- Colitis
- Chronic diarrhea
- Presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction
- Patients with bleeding or clotting tendencies
- Organ transplantation
- Presence of circulating coagulation inhibitors

4. A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:

- Evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy.
- Prior to the use of thrombolytic medication

Limitations

1. When an ESRD patient is tested for PT, testing more frequently than weekly (the frequency authorized by 3171.2, Fiscal Intermediary Manual, or 2231.3 Medicare Carrier Manual) requires documentation of medical necessity [e.g. other than ''Chronic Renal Failure'' (ICD–9–CM 585) or ''Renal Failure, Unspecified'' (ICD–9–CM 586)].

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of warfarin. In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks. When testing is performed to evaluate a patient with signs or symptoms of abnormal bleeding or thrombosis and the initial test result is normal, it is ordinarily not necessary to repeat testing unless there is a change in the patient's medical status.

3. Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional prothrombin time, 85610.

4. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy.

Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
002.0—002.9	Typhoid and paratyphoid
003.0—003.9	Other Salmonella infections
038.9	Unspecified Septicemia
042	Human Immunodeficiency virus (HIV) disease
060.0—060.9	Yellow fever
065.0–065.9	Arthropod-borne hemorrhagic fever
070.0–070.9	Viral hepatitis
075	Infectious mononucleosis
078.6	Hemorrhagic nephrosonephritis
078.7	Arenaviral hemorrhagic fever
084.8	Blackwater fever
120.0	Schistosomiasis
121.1	Clonorchiasos
121.3	Fascioliasis
124	Trichinosis
134.2	Hirudiniasis
135	Sarcoidosis
152.0–152.9	Malignant neoplasm of small intestine, including duodenum
155.0–155.2	Malignant neoplasm of liver and intrahepatic bile ducts
156.0–156.9	Malignant neoplasm of gallbladder and extrahepatic bile ducts
157.0–157.9	Malignant neoplasm of pancreas
188.0–189.9	Malignant neoplasm of bladder, kidney, and other and unspecified urinary organs
198.0	Secondary malignant neoplasm, kidney
198.1	Secondary malignant neoplasm, other urinary organs
200.00–200.88	Lymphosarcoma and reticulosarcoma
202.0–202.98	Nodular and other Lymphomas
223.0–223.9	Benign neoplasm of kidney and other urinary organs
238.4	Polycythemia vera
238.5	Histocytic and mast cells—neoplasm of uncertain behavior
238.6	Plasma cells—neoplasm of uncertain behavior
238.7	Other lymphatic and hematopoietic tissues
239.4	Neoplasm of unspecified nature, bladder
239.5	Neoplasm of unspecified nature, other genitourinary organs
239.9	Neoplasm of unspecified nature, site unspecified
246.3	Hemorrhage and infarction of thyroid
250.40–250.43	Diabetic with renal manifestations
263.0–263.9	Other and unspecified protein/calorie malnutrition
269.0	Deficiency of Vitamin K
269.2	Unspecified vitamin deficiency
273.0–273.9	Disorders of plasma protein metabolism
275.0	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism
277.3	Amyloidosis
280.0	Iron deficiency anemia, secondary to blood loss—chronic
280.9	Iron deficiency anemia, unspecified
281.0	Pernicious anemia
281.1	Other Vitamin B12 Deficiency Anemia, NEC
281.9	Unspecified Deficiency Anemia, NOS
285.0	Sideroblastic anemia
285.1	Acute posthemorrhagic anemia
286.0–286.9	Coagulation defects
287.0–287.9	Purpura and other hemorrhagic conditions
290.40–290.43	Arteriosclerotic dementia
325	Phlebitis and thrombophlebitis of intracranial venous sinuses
342.90–342.92	Hemiplegia NOS
360.43	Hemophthalmios, except current injury
362.18	Retinal vasculitis
362.30–362.37	Retinal vascular occlusion
362.43	Hemorrhagic detachment of retnal pigment epithelium
362.81	Retinal hemorrhage
363.61–363.72	Choroidal hemorrhage and rupture, detachment
368.9	Unspecified Visual Disturbances
372.72	Conjunctival hemorrhage

Code	Description
374.81	Hemorrhage of eyelid
376.32	Orbital hemorrhage
377.42	Hemorrhage in optic nerve sheaths
377.53	Disorders of optic chiasm associated with vascular disorders
377.62	Disorders of visual pathways associated with vascular disorders
377.72	Disorders of visual cortex associated with vascular disorders
379.23	Vitreous hemorrhage
380.31	Hematoma of auricle or pinna
386.2	Vertigo of central origin
386.50	Labyrinthine dysfunction, unspecified
394.0–394.9	Diseases of the mitral valve
395.0	Rheumatic aortic stenosis
395.2	Rheumatic aortic stenosis with insufficiency
396.0–396.9	Diseases of mitral and aortic valves
397.0–397.9	Diseases of other endocardial structures
398.0–398.99	Other rheumatic heart disease
403.01, 403.11, 403.91	Hypertensive Renal Disease with renal failure
404.02, 404.12, 404.92	Hypertensive Heart and Renal Disease with renal failure
410.00–410.92	Acute myocardial infarction
411.1	Intermediate coronary syndrome
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
413.0–413.9	Angina pectoris
414.00–414.05	Coronary atherosclerosis
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
415.0–415.19	Acute pulmonary heart disease
416.9	Chronic pulmonary heart disease, unspecified
423.0	Hemopericardium
424.0	Mitral valve disorders
424.1	Aortic valve disorder
424.90	Endocarditis, valve unspecified, unspecified cause
425.0–425.9	Cardiomyopathy
427.0–427.9	Cardiac dysrhythmias
1428.0–428.9	Heart failure
429.0–429.4	Ill-defined descriptions and complications of heart disease
429.79	Other certain sequelae of myocardial infarction, not elsewhere classified
430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432.0–432.9	Other and unspecified intracranial hemorrhage
433.00–433.91	Occlusion and stenosis of precerebral arteries
434.00–434.91	Occlusion of cerebral arteries
435.0–435.9	Transient cerebral ischemia
436	Acute, but ill-defined cerebrovascular disease
437.0	Cerebral atherosclerosis
437.1	Other generalized ischemic cerebrovascular disease
437.6	Nonpyogenic thrombosis of intracranial venous sinus
440.0–440.9	Atherosclerosis
441.0–441.9	Aortic aneurysm and dissection
443.0–443.9	Other peripheral vascular disease
444.0–444.9	Arterial embolism and thrombosis
447.1	Stricture of artery
447.2	Rupture of artery
447.6	Arteritis, unspecified
448.0	Hereditary hemorrhagic telangiectasia
448.9	Other and unspecified capillary diseases
451.0–451.9	Phlebitis and thrombophlebitis
452	Portal vein thrombosis
453.0–453.9	Other venous embolism and thrombosis
455.2	Internal hemorrhoids with other complication
455.5	External hemorrhoids with other complication
455.8	Unspecified hemorrhoids with other complication
456.0–456.1	Esophageal varices
456.8	Varices of other sites
459.0	Hemorrhage, unspecified
459.1	Postphlebitis syndrome
459.2	Compression of vein
459.81	Venous (peripheral) insufficiency, unspecified
459.89	Other, other specified disorders of circulatory system
511.8	Other specified forms of effusion, except tuberculosis
514	Pulmonary congestion and hypostasis
530.7	Gastroesophageal laceration—hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00–535.61	Gastric ulcer, duodenal ulcer, peptic ulcer, gastrojejunal ulcer, gastritis and duodenitis

Code	Description
555.0–555.9	Regional enteritis
556.0–556.9	Ulcerative colitis
557.0–557.9	Vascular insufficiency of intestine
562.02—562.03	Diverticulosis of small intestine with hemorrhage
562.10	Diverticulosis of colon w/o hemorrhage
562.11	Diverticulitis of colon w/o hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
568.81	Hemoperitoneum (nontraumatic)
569.3	Hemorrhage of rectum and anus
571.0–571.9	Chronic liver disease and cirrhosis
572.2	Hepatic coma
572.4	Hepatorenal syndrome
572.8	Other sequelae of chronic liver disease
573.1–573.9	Hepatitis in viral diseases, other and unspecified disorder of liver
576.0–576.9	Other disorders of Biliary tract
577.0	Acute pancreatitis
578.0–578.9	Gastrointestinal hemorrhage
579.0–579.9	Intestinal Malabsorption
581.0–581.9	Nephrotic Syndrome
583.9	Nephritis, with unspecified pathological lesion in kidney
584.5–584.9	Acute Renal Failure
585	Chronic Renal Failure
586	Renal failure, unspecified
593.81–593.89	Other specified disorders of kidney and ureter
596.7	Hemorrhage into bladder wall
596.8	Other specified disorders of bladder
599.7	Hematuria
607.82	Vascular disorders of penis
608.83	Vascular disorders of male genital organs
611.8	Other specified disorders of breast—hematoma
620.7	Hemorrhage of broad ligament
621.4	Hematometra
622.8	Other specified noninflammatory disorders of cervix
623.6	Vaginal hematoma
623.8	Other specified noninflammatory disorders of the vagina
624.5	Hematoma of vulva
626.2–626.9	Abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
629.0	Hematocele female, not classified elsewhere
632	Missed abortion
634.10–634.12	Spontaneous abortion, complicated by excessive hemorrhage
635.10–635.12	Legally induced abortion, complicated by delayed or excessive hemorrhage
636.10–636.12	Illegally induced abortion, complicated by delayed or excessive hemorrhage
637.10–637.12	Abortion unspecified, complicated by delayed or excessive hemorrhage
638.1	Failed attempted abortion, complicated by delayed or excessive hemorrhage
639.1	Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies
639.6	Complications following abortion and ectopic and molar pregnancies with embolism
640.00–640.93	Hemorrhage in early pregnancy
641.00–641.93	Antepartum hemorrhage, abruptio placentae, and placenta previa
642.00–642.94	Hypertension complicating pregnancy, childbirth, and the puerperium
646.70–646.73	Liver disorders in pregnancy
656.00–656.03	Fetal maternal hemorrhage
658.40–658.43	Infection of amniotic cavity
666.00–666.34	Postpartum hemorrhage
671.20–671.94	Venous complications in pregnancy and the puerperium
673.00–673.84	Obstetrical pulmonary embolism
674.30–674.34	Other complications of obstetrical surgical wounds
713.2	Arthropathy associated with hematological disorders
713.6	Arthropathy associated with hypersensitivity reaction
719.15	Hemarthrosis pelvic region and thigh
719.16	Lower leg
719.19	Multiple sites
729.5	Pain in limb
733.1	Patholgic fracture, unspecified site
746.00–746.9	Other Congenital anomalies of heart
762.1	Other forms of placental separation and hemorrhage
767.0–767.1	Subdural and cerebral hemorrhage
767.8	Other specified birth trauma
770.3	Pulmonary hemorrhage
772.0–772.9	Fetal and neonatal hemorrhage
774.6	Unspecified fetal and neonatal jaundice
776.0–776.9	Hemorrhagic disease of the newborn

Code	Description
780.2	Syncope and collapse
782.3	Edema
782.4	Jaundice, unspecified, not of newborn
782.7	Spontaneous ecchymosis
784.7	Epistaxis
784.8	Hemorrhage from throat
785.4	Gangrene
785.50	Shock without mention of trauma
786.05	Shortness of breath
786.3	Hemoptysis
786.59	Chest pain, other
789.00–789.09	Abdominal pain
789.1	Hepatomegaly
789.5	Ascites
790.92	Abnormal coagulation profile
790.94	Euthyroid sick syndrome
791.2	Hemoglobinuria
794.8	Abnormal Liver Function Study
800.00–800.99	Fracture of vault of skull
801.00–801.99	Fracture of base of skull
802.20–802.9	Fracture of face bones
803.00–803.99	Other and unqualified skull fractures
804.00–804.99	Multiple fractures involving skull or face with other bones
805.00–806.9	Fracture, vertebral column
807.00–807.09	Fractures of rib(s), closed
807.10–807.19	Fracture of rib(s), open
808.8–808.9	Fracture of Pelvis
809.0–809.1	Ill-defined fractures of bones of Trunk
810.00–810.13	Fracture of Clavicle
811.00–811.19	Fracture of Scapula
812.00–812.59	Fracture of Humerus
813.10–813.18	Fracture of radius and ulna, upper end, open
813.30–813.38	Shaft, open
813.50–813.58	Lower end, open
813.90–813.98	Fracture unspecified part, open
819.0–819.1	Multiple fractures involving both upper limbs, closed and open
820.00–821.39	Fracture of neck of femur
823.00–823.92	Fracture of tibia and fibula
827.0–829.1	Other multiple lower limb
852.00–852.59	Subarachnoid, subdural, and extradural hemorrhage, following injury
853.00–853.19	Other and specified intracranial hemorrhage following injury
852.00–853.19	Subarachnoid subdural, and extradural hemorrhage, following injury, Other and specified intracranial hemorrhage following injury
860.0–860.5	Traumatic pneumothorax and hemothorax
861.00–861.32	Injury to heart and lung
862.0–862.9	Injury to other and unspecified intrathoracic organs
863.0–863.9	Injury to gastrointestinal tract
864.00–864.19	Injury to liver
865.00–865.19	Injury to spleen
866.00–866.13	Injury to kidney
867.0–867.9	Injury to pelvic organs
868.00–868.19	Injury to other intra-abdominal organs
869.0–869.1	Internal injury to unspecified or ill defined organs
900.00–900.9	Injury to blood vessels of head and neck
901.0–901.9	Injury to blood vessels of the thorax
902.0–902.9	Injury to blood vessels of the abdomen and pelvis
903.00–903.9	Injury to blood vessels of upper extremity
904.0–904.9	Injury to blood vessels of lower extremity and unspecified sites
920–924.9	Contusion with intact skin surface
925.1–929.9	Crushing injury
958.2	Secondary and recurrent hemorrhage
959.9	Injury, unspecified site
964.0–964.9	Poisoning by agents primarily affecting blood constituents
980.0–980.9	Toxic effect of alcohol
981	Toxic effect of petroleum products
982.0–982.8	Toxic effects of solvents other than petroleum-based
987.0–987.9	Toxic effect of other gases, fumes or vapors
989.0–989.9	Toxic effect of other substances chiefly non-medicinal as to source
995.2	Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered)
996.82	Complication of transplanted liver
997.4	Digestive system complications
998.11–998.12	Hemorrhage or hematoma complicating a procedure
997.02	Iatrogenic cerbrovascular infarction or hemorrhage

Code	Description
999.2	Other vascular complications
999.8	Other transfusion reactions
V08	Asymptomatic HIV infection
V12.1	History of nutritional deficiency
V12.3	Personal history of diseases of blood and blood-forming organs
V12.50–V12.59	Diseases of circulatory system
V15.1	Personal history of surgery to heart and great vessels
V15.2	Personal history of surgery of other major organs
V42.0	Kidney replaced by transplant
V42.1	Heart replaced by transplant
V42.2	Heart valve replaced by transplant
V42.6	Lung replaced by transplant
V42.7	Liver replaced by transplant
V42.8	Other specified organ or tissue replaced by transplant
V43.2	Heart replaced by other means
V43.3	Heart valve replaced by other means
V43.4	Blood vessel replaced by other means
V43.60	Unspecified joint replaced by other means
V58.2	Transfusion of blood products
V58.61	Long-term (current) use of anticoagulants
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons

Code	Description
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

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''Monitoring Oral Anticoagulation Therapy with Point-of-Care Devices. Correlation and Caveats''. Clinical Chemistry: No. 9, 1997, p1785–1786.

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''A Structured Teaching and Self-management Program for Patients Receiving Oral Anti-coagulation''. JAMA; 1999; 281: 145–150.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. If a specific condition is known and is the reason for a pre-operative test, submit the text description or ICD–9–CM code describing the condition with the order/referral. If a specific condition or disease is not known, and the pre-operative test is for pre-operative clearance only, assign code V72.84.

7. Assign codes 289.8—other specified disease of blood and blood-forming organs only when a specific disease exists and is indexed to 289.8 (for example, myelofibrosis). Do not assign code 289.8 to report a patient on long term use of anticoagulant therapy (e.g. to report a PT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PT checks or re-checks. (Reference AHA's Coding Clinic, March-April, pg 12—1987, 2nd quarter pg 8—1989)

Medicare National Coverage Decision for Serum Iron Studies

Other Names/Abbreviations

Description

Serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron studies are best performed when the patient is fasting in the morning and has abstained from medications that may influence iron balance.

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary

deficiency or malabsorption. Following major surgery the patient may have iron deficient erythropoiesis for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

Total iron binding capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, and with oral contraceptive use, and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

Assays for ferritin are also useful in assessing iron balance. Low concentrations are associated with iron deficiency and are highly specific. High concentrations are found in hemosiderosis (iron overload without associated tissue injury) and hemochromatosis (iron overload with associated tissue injury). In these conditions the iron is elevated, the TIBC and transferrin are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload. ransferrin and ferritin belong to a group of serum proteins known as acute phase reactants, and are increased in response to stressful or inflammatory conditions and also can occur with infection and tissue injury due to surgery, trauma or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions, and in patients with these disorders, tests of iron status may be difficult to interpret.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82728	Ferritin
83540	Iron
83550	Iron Binding capacity
84466	Transferrin

Indications

1. Ferritin (82728), iron (83540) and either iron binding capacity (83550) or transferrin (84466) are useful in the differential diagnosis of iron deficiency, anemia, and for iron overload conditions.

A. The following presentations are examples that may support the use of these studies for evaluating iron deficiency:

- Certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV).
- Abnormal appetite (pica)
- Acute or chronic gastrointestinal blood loss
- Hematuria
- Menorrhagia
- Malabsorption
- Status post-gastrectomy
- Status post-gastrojejunostomy
- Malnutrition
- Preoperative autologous blood collection(s)
- Malignant, chronic inflammatory and infectious conditions Associated with anemia which may present in a similar manner to iron deficiency anemia
- Following a significant surgical procedure where blood loss had occurred and had not been repaired with adequate iron replacement.

B. The following presentations are examples that may support the use of these studies for evaluating iron overload:

- Chronic Hepatitis
- Diabetes
- Hyperpigmentation of skin
- Arthropathy
- Cirrhosis
- Hypogonadism
- Hypopituitarism
- Impaired porphyrin metabolism
- Heart failure
- Multiple transfusions
- Sideroblastic anemia
- Thalassemia major
- Cardiomyopathy, cardiac dysrhythmias and conduction distrubances

2. Follow-up testing may be appropriate to monitor response to therapy, e.g., oral or parenteral iron, ascorbic acid, and erythropoietin.

3. Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.

4. Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.

5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (e.g., nickel, cadmium, aluminum, lead) whether due to accidental, intentional exposure or metabolic causes.

Limitations

1. Iron studies should be used to diagnose and manage iron deficiency or iron overload states. These tests are not to be used solely to assess acute phase reactants where disease management will be unchanged. For example, infections and malignancies are associated with elevations in acute phase reactants such as ferritin, and decreases in serum iron concentration, but iron studies would only be medically necessary if results of iron studies might alter the management of the primary diagnosis or might warrant direct treatment of an iron disorder or condition.

2. If a normal serum ferritin level is documented, repeat testing would not ordinarily be medically necessary unless there is a change in the patient's condition, and ferritin assessment is needed for the ongoing management of the patient. For example, a patient presents with new onset insulin-dependent diabetes mellitus and has a serum ferritin level performed for the suspicion of hemochromatosis. If the ferritin level is normal, the repeat ferritin for diabetes mellitus would not be medically necessary.

3. When an End Stage Renal Disease (ESRD) patient is tested for ferritin, testing more frequently than every three months (the frequency authorized by 3167.3, Fiscal Intermediary manual) requires documentation of medical necessity [e.g., other than ''Chronic Renal Failure'' (ICD–9–CM 585) or ''Renal Failure, Unspecified'' (ICD–9–CM 586)].

4. It is ordinarily not necessary to measure both transferrin and TIBC at the same time because TIBC is an indirect measure of transferrin. When transferrin is ordered as part of the nutritional assessment for evaluating malnutrition, it is not necessary to order

other iron studies unless iron deficiency or iron overload is suspected as well.

5. It is not ordinarily necessary to measure both iron/TIBC (or transferrin) and ferritin in initial patient testing. If clinically indicated after evaluation of the initial iron studies, it may be appropriate to perform additional iron studies either on the initial specimen or on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferrin) or ferritin may be medically necessary for monitoring, but not both.

6. It would not ordinarily be considered medically necessary to do a ferritin as a preoperative test except in the presence of anemia or recent autologous blood collections prior to the surgery.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
002.0–002.9	Typhoid and paratyphoid fevers
003.0–003.9	Other salmonella infections
006.0–006.9	Amebiasis
007.0–007.9	Other protozoal intestinal diseases
008.00–008.8	Intestinal infections due to other organisms
009.0–009.3	Ill-defined intestinal infections
011.50–011.56	Tuberculous bronchiectasis
014.00–014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
015.00–015.96	Tuberculosis of bones and joints
016.00–016.06	Tuberculosis of kidney
016.10–016.16	Tuberculosis of bladder
016.20–016.26	Tuberculosis of ureter
016.30–016.36	Tuberculosis of other urinary organs
042	Human Immunodeficiency virus (HIV) disease
070.0–070.9	Viral hepatitis
140.0–149.9	Malignant neoplasm of lip oral cavity and pharynx
150.0–159.9	Malignant neoplasm of digestive organs and peritoneum
160.0–165.9	Malignant neoplasm of respiratory and intrathoracic organs
170.0–176.9	Malignant neoplasm of bone, connective tissue, skin and breast
179–189.9	Malignant neoplasm of genitourinary organs
190.0–199.1	Malignant neoplasm of other and unspecified sites
200.0–208.91	Malignant neoplasm of lymphatic and hematopoietic tissue
210.0–229.9	Benign neoplasms
230.0–234.9	Carcinoma in situ
235.0–238.9	Neoplasms of uncertain behavior
239.0–239.9	Neoplasms of unspecified nature
250.00–250.93	Diabetes mellitus
253.2	Panhypopituitarism
253.7	Iatrogenic pituitary disorders
253.8	Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin
256.3	Other ovarian failure
257.2	Other testicular hypofunction
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe protein-calorie malnutrition
263.0–263.9	Other and unspecified protein-calorie malnutrition
275.0	Disorders of iron metabolism
277.1	Disorders of porphyrin metabolism
280.0–280.9	Iron deficiency anemias
281.0–281.9	Other deficiency anemias
282.4	Thalassemias
285.0	Sideroblastic anemia (includes hemochromatosis with refractory anemia)
285.1	Acute post-hemorrhagic anemia
285.9	Anemia, unspecified
286.0–286.9	Coagulation defects (congenital factor disorders)
287.0–287.9	Purpura and other hemorrhagic conditions
306.4	Physiological malfunction arising from mental factors, gastrointestinal
307.1	Anexoria nervosa
307.50–307.59	Other and unspecified disorders of eating
425.4	Other primary cardiomyopathies
425.5	Alcoholic cardiomyopathy
425.7	Nutritional and metabolic cardiomyopathy
425.8	Cardiomyopathy in other diseases classified elsewhere
425.9	Secondary cardiomyopathy, unspecified
426.0–426.9	Conduction disorders
427.0–427.9	Cardiac dysrhythmias
428.0–428.9	Heart Failure
530.7	Gastroesophageal laceration-hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00–531.91	Gastric ulcer
532.00–532.91	Duodenal ulcer
533.00–533.91	Peptic ulcer, site unspecified

Code	Description
534.00–534.91	Gastrojejunal ulcer
535.00–535.61	Gastritis and duodenitis
536.0–536.9	Disorders of function of stomach
537.83	Angiodysplasia of stomach and duodenum with hemorrhage
555.0–555.9	Regional enteritis
556.0–556.9	Ulcerative colitis
557.0	Acute vascular insufficiency of intestine
557.1	Chronic vascular insufficiency of intestine
562.02	Diverticulosis of small intestine without hemorrhage
562.03	Diverticulitis of small intestine without hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
569.3	Hemorrhage of rectum and anus
569.85	Angiodysplasia of intestine with hemorrhage
570	Acute and subacute necrosis of liver
571.0–571.9	Chronic liver disease and cirrhosis
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.0–573.9	Other disorders of liver
578.0–578.9	Gastrointestinal hemorrhage
579.0–579.3	Intestinal malabsorption
579.8–579.9	Other specified and unspecified intestinal malabsorption
581.0–581.9	Nephrotic syndrome
585	Chronic renal failure
586	Renal failure, unspecified
608.3	Atrophy of testis
626.0–626.9	Disorders of menstruation and other abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
648.20–648.24	Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium: Anemia
698.0–698.9	Pruritis and related conditions
704.00–704.09	Alopecia
709.00–709.09	Dyschromia
713.0	Arthropathy associated with other endocrine and matabolic disorders
716.40–716.99	Other and unspecified arthropathies
719.40–719.49	Pain in joint
773.2	Hemolytic disease due to other and unspecified isoimmunization
773.3	Hydrops fetalis due to isoimmunization
773.4	Kernicterus due to isoimmunization
773.5	Late anemia due to isoimmunization
783.9	Other symptoms concerning nutrition, metabolism and development
790.0	Abnormality of red blood cells
790.4	Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase [LDH]
790.5	Other nonspecific abnormal serum enzyme levels
790.6	Other abnormal blood chemistry
799.4	Cachexia
964.0	Poisoning by agents primarily affecting blood constituents, iron compounds
984.0–984.9	Toxic effect of lead and its compounds (including fumes)
996.85	Complications of transplanted organ, bone marrow
999.8	Other transfusion reaction
V08	Asymptomatic HIV infection
V12.1	Personal history of nutritional deficiency
V12.3	Personal history of diseases of blood and blood forming organs
V15.1	Personal history of surgery to heart and great vessels
V15.2	Personal history of surgery to other major organs
V43.2	Heart replaced by other means
V43.3	Heart valve replaced by other means
V43.4	Blood vessel replaced by other means
V43.60	Unspecified joint replaced by other means
V56.0	Extracorporeal dialysis
V56.8	Other dialysis
V72.84	Pre-operative examination, unspecified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result

in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

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Coding Guidelines

1. Any claim for a test listed in AHCPCS CODES@ above must be submitted with an ICD–9–CM diagnosis

code or comparable narrative. ICD–9–CM code V82.9 (special screening of other conditions, unspecified condition), or comparable narratives should be used to indicate screening tests performed in the absence of a specific sign, symptom, or complaint. Use of V82.9 or comparable narrative will result in the denial of claims as non covered screening services. (**Note:** this language may be inappropriate for screening tests that are specifically covered by statute, such as pap smears.) All ICD–9–CM diagnosis codes must be coded to the highest level of specificity.

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit or fifth-digit classifications are provided, they must be assigned. From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Collagen Crosslinks, Any Method

Other Names/Abbreviations

Description

Collagen crosslinks, part of the matrix of bone upon which bone mineral is deposited, are biochemical markers the excretion of which provide a quantitative measurement of bone resorption. Elevated levels of urinary collagen crosslinks indicate elevated bone resorption. Elevated bone resorption contributes to age-related and postmenopausal loss of bone leading to osteoporosis and increased risk of fracture. The collagen crosslinks assay can be performed by immunoassay or by high performance liquid chromatography (HPLC). Collagen crosslink immunoassays measure the pyridinoline crosslinks and associated telopeptides in urine.

Bone is constantly undergoing a metabolic process called turnover or remodeling. This includes a degradation process, bone resorption, mediated by the action of osteoclasts, and a building process, bone formation, mediated by the action of osteoblasts. Remodeling is required for the maintenance and overall health of bone and is tightly coupled; that is, resorption and formation must be in balance. In abnormal states of bone remodeling, when resorption exceeds formation, it results in a net loss of bone. The measurement of specific, bone-derived resorption products provides analytical data about the rate of bone resorption.

Osteoporosis is a condition characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. The term primary osteoporosis is applied where the causal factor in the disease is menopause or aging. The term secondary osteoporosis is applied where the causal factor is something other than menopause or aging, such as long-term administration of glucocorticosteroids, endocrine-related disorders (other than loss of estrogen due to menopause), and certain bone diseases such as cancer of the bone.

With respect to quantifying bone resorption, collagen crosslink tests can provide adjunct diagnostic information in concert with bone mass measurements. Bone mass measurements and biochemical markers may have complementary roles to play in assessing effectiveness of osteoporosis treatment. Proper management of osteoporosis patients, who are on long-term therapeutic regimens, may include laboratory testing of biochemical markers of bone turnover, such as collagen crosslinks, that provide a profile of bone turnover responses within weeks of therapy. Changes in collagen crosslinks are determined following commencement of antiresorptive therapy. These can be measured over a shorter time interval, such as three months, when compared to bone mass density. If bone resorption is not elevated, repeat testing is not medically necessary.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
82523	Collagen cross links, any method

Indications

Generally speaking, collagen crosslink testing is useful mostly in ''fast losers'' of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless. Coverage for bone marker assays may be established, however, for younger Medicare beneficiaries and for those men and women who might become fast losers because of some other therapy such as glucocorticoids. Safeguards should be incorporated to prevent excessive use of tests in patients for whom they have no clinical relevance. Collagen crosslinks testing is used to:

- Identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored;
- Predict response (as assessed by bone mass measurements) to FDA approved antiresorptive therapy in postmenopausal women;

• Assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or risk for osteoporosis where treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogen receptor moderators.

Limitations

Because of significant specimen to specimen collagen crosslink physiologic variability (15–20%), current recommendations for appropriate utilization include: one or two base-line assays from specified urine collections on separate days; followed by a repeat assay about three months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the three-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated three months after the initiation of new therapy.

Some collagen crosslink assays may not be appropriate for use in some disorders, according to FDA labeling restrictions.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–242.91	Thyrotoxicosis
245.2	Chronic lymphocytic thyroiditis (only if thyrotoxic)
246.9	Unspecified disorder of thyroid
252.0	Hyperparathyroidism
256.2	Postablative ovarian failure
256.3	Other ovarian failure
256.8	Other ovarian dysfunction
256.9	Unspecified ovarian dysfunction
268.9	Unspecified vitamin D deficiency
269.3	Mineral deficiency, not elsewhere classified
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
627.2	Menopausal or female climacteric state
627.4	States associated with artificial menopause
627.8	Other specified menopausal and postmenopausal disorders
627.9	Unspecified menopausal & postmenopausal disorder
731.0	Osteitis deformans without mention of bone tumor (Paget's disease of bone)
733.00–733.09	Osteoporosis
733.10–733.19	Pathological fracture
733.90	Disorder of bone and cartilage, unspecified
805.8	Fracture of vertebral column without mention of spiral cord injury, unspecified, closed
V58.69	Long-term (current) use of other medications

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs

Code	Description
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections.

Sources of Information

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Schneider DL, Barrett-Connor EL. Urinary N-Telopeptide levels discriminate normal, osteopenic, and osteoporotic bone mineral density. Arch. Intern. Med. 1997;157:1241–5.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it

has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When the indication for the test is long-term administration of glucocorticosteroids, use ICD–9–CM code V58.69.

Medicare National Coverage Decision for Blood Glucose Testing

Description

This policy is intended to apply to blood samples used to determine glucose levels.

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison of an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

HCPCS Codes (Alpha numeric, CPT–AMA)

Code	Descriptor
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose; blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use.

Indications

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110–125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause). Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

Limitations

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

ICD–9–CM Codes Covered by Medicare Program

Code	Description
011.00–011.96	Tuberculosis
038.0–038.9	Septicemia
112.1	Recurrent vaginal candidiasis
112.3	Interdigital candidiasis
118	Opportunistic mycoses
157.4	Malignant neoplasm of Islets of Langerhans
158.0	Malignant neoplasm of retroperitoneum
211.7	Benign neoplasm of Islets of Langerhans
242.00–242.91	Thyrotoxicosis
250.00–250.93	Diabetes mellitus
251.0–251.9	Disorders of pancreatic internal secretion
253.0–253.9	Disorders of the pituitary gland
255.0	Cushing syndrome

Code	Description
263.0–263.9	Malnutrition
271.0–271.9	Disorders of carbohydrate transport and metabolism
272.0–272–4	Disorders of lipoid metabolism
275.0	Hemochromotosis
276.0–276.9	Disorders of fluid, electrolyte and acid-base balance
278.3	Hypercarotinemia
293.0	Acute delirium
294.9	Unspecified organic brain syndrome
298.9	Unspecified psychosis
300.9	Unspecified neurotic disorder
310.1	Organic personality syndrome
337.9	Autonomic nervous system neuropathy
345.10–345.11	Generalized convulsive epilepsy
348.3	Encephalopathy, unspecified
355.9	Neuropathy, not otherwise specified
356.9	Unspecified hereditary and idiopathic peripheral neuropathy
357.9	Unspecified inflammatory and toxic neuropathy
362.10	Background retinopathy
362.18	Retinal vasculitis
362.29	Nondiabetic proliferative retinopathy
362.50–362.57	Degeneration of macular posterior pole
362.60–362.66	Peripherial retinal degeneration
362.81–362.89	Other retinal disorders
362.0	Unspecified retinal disorders
365.04	Borderline glaucoma, ocular hypertension
365.32	Corticosteriod-induced glaucoma residual
366.00–366.09	Presenile cataract
366.10–366.19	Senile cataract
367.1	Acute myopia
368.8	Other specified visual disturbance
373.00	Blepharitis
377.24	Pseudopapilledema
377.9	Autonomic nervous system neuropathy
378.50–378.55	Paralytic strabiamus
379.45	Argyll-Robertson pupils
410.00–410.92	Acute myocardial infarctions
414.00–414.19	Coronary atherosclerosis and aneurysm of heart
425.9	Secondary cardiomyopathy, unspecified
440.23	Arteriosclerosis of extremities with ulceration
440.24	Arteriosclerosis of extremities with gangrene
440.9	Arteriosclerosis, not otherwise specified
458.0	Postural hypotension
462	Acute pharyngitis
466.0	Acute bronchitis
480.0–486	Pneumonia
490	Recurrent bronchitis, not specified as acute or chronic
491.0–491.9	Chronic bronchitis
527.7	Disturbance of salivory secretion (drymouth)
528.0	Stomatitis
535.50–535.51	Gastritis
536.8	Dyspepsia
571.8	Other chronic nonalcoholic liver disease
572.0–572.8	Liver abscess and sequelae of chronic liver disease
574.50–574.51	Choledocholitiasis
575.0–575.12	Cholecystitis
576.1	Cholangitis
577.0	Acute pancreatitis
577.1	Chronic pancreatitis
577.8	Pancreatic multiple calculi
590.00–590.9	Infections of the kidney
595.9	Recurrent cystitis
596.4	Bladder atony
596.53	Bladder paresis
599.0	Urinary tract infection, recurrent
607.84	Impotence of organic origin
608.89	Other disorders male genital organs
616.10	Vulvovaginitis
626.0	Amenorrhea
626.4	Irregular menses
628.9	Infertility—female
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antipartum condition or complication

Code	Description
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antipartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
656.60–656.63	Fetal problems affecting management of mother—large for-date of fetus
657.00–657.03	Polyhydramnios
680.0–680.9	Carbuncle and furuncle
686.00–686.9	Infections of skin and subcutaneous tissue
698.0	Pruritis ani
698.1	Pruritis of genital organs
704.1	Hirsutism
705.0	Anhidrosis
707.0–707.9	Chronic ulcer of skin
709.3	Degenerative skin disorders
729.1	Myalgia
730.07–730.27	Osteomyelitis of tarsal bones
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.2	Syncope and collapse
780.31	Febrile convulsions
780.39	Seizures, not otherwise specified
780.4	Dizziness and giddiness
780.71–780.79	Malaise and fatigue
780.8	Hyperhidrosis
781.0	Abnormal involuntary movements
782.0	Loss of vibratory sensation
783.1	Abnormal weight gain
783.2	Abnormal loss of weight
783.5	Polydipsia
783.6	Polyphagia
785.0	Tachycardia
785.4	Gangrene
786.01	Hyperventilation
786.09	Dyspnea,
786.50	Chest pain, unspecified
787.6	Fecal incontinence
787.91	Diarrhea
788.41–788.43	Frequency of urination and polyuria
789.1	Hepatomegaly
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemia)
791.0	Proteinuria
791.5	Glycosuria
796.1	Abnormal reflex
799.4	Cachexia
V23.0–.9	Supervision of high risk pregnancy
V67.2	Follow-up examination, following chemotherapy
V67.51	Follow up examination with high-risk medication not elsewhere classified
V58.69	Long term current use of other medication

Reasons for Denial:

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a

claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

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Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pages 1183 *et seq.*

Roberts, H.J., Difficult Diagnoses. W. B. Saunders Co., pp 69–70.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided.

Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44).

4. Diagnoses documented as ''probable,'' ''suspected,' questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

7. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

8. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

9. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

10. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement, ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

Documentation Requirements

The ordering physician must include evidence in the patient's clinical record that an evaluation of history and physical preceded the ordering of glucose testing and that manifestations of abnormal glucose levels were present to warrant the testing.

Medicare National Coverage Decision for Glycated Hemoglobin/glycated Protein

Description

The management of diabetes mellitus requires regular determinations of blood glucose levels. Glycated hemoglobin/protein levels are used to assess long-term glucose control in diabetes. Alternative names for these tests include glycated or glycosylated hemoglobin or Hgb, hemoglobin glycated or glycosylated protein, and fructosamine.

Glycated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis.

Fructosamine or glycated protein refers to glycosylated protein present in a serum or plasma sample. Glycated protein refers to measurement of the component of the specific protein that is glycated usually by colorimetric method or affinity chromatography.

Glycated hemoglobin in whole blood assesses glycemic control over a period of 4–8 weeks and appears to be the more appropriate test for monitoring a patient who is capable of maintaining long-term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1–2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1–2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82985	Glycated protein
83036	Hemoglobin; glycated

Indications

Glycated hemoglobin/protein testing is widely accepted as medically necessary for the management and control of diabetes. It is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Glycated protein testing may be used in place of glycated hemoglobin in the management of diabetic patients, and is particularly useful in patients who have abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

Limitations

It is not considered reasonable and necessary to perform glycated hemoglobin tests more often than every

three months on a controlled diabetic patient to determine whether the patient's metabolic control has been on average within the target range. It is not considered reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women. Testing for uncontrolled type one or two diabetes mellitus may require testing more than four times a year. The above Description Section provides the clinical basis for those situations in which testing more frequently than four times per annum is indicated, and medical necessity documentation must support such testing in excess of the above guidelines.

Many methods for the analysis of glycated hemoglobin show significant interference from elevated levels of fetal hemoglobin or by variant hemoglobin molecules. When the glycated hemoglobin assay is initially performed in these patients, the laboratory may inform the ordering physician of a possible analytical interference. Alternative testing, including glycated protein, for example, fructosamine, may be indicated for the monitoring of the degree of glycemic control in this situation. It is therefore conceivable that a patient will have both a glycated hemoglobin and glycated protein ordered on the same day. This should be limited to the initial assay of glycated hemoglobin, with subsequent exclusive use of glycated protein.

These tests are not considered to be medically necessary for the diagnosis of diabetes.

ICD–9–CM Codes Covered by the Medicare Program

Code	Description
211.7	Benign neoplasm of islets of Langerhans
250.00–250.93	Diabetes mellitus & various related codes
251.0	Hypoglycemic coma
251.1	Other specified hypoglycemia
251.2	Hypoglycemia unspecified
251.3	Post-surgical hypoinsulinemia
251.4	Abnormality of secretion of glucagon
251.8	Other specified disorders of pancreatic internal secretion
251.9	Unspecified disorder of pancreatic internal secretion
258.0–258.9	Polyglandular dysfunction
271.4	Renal glycosuria
275.0	Hemochromatosis
577.1	Chronic pancreatitis
579.3	Other and unspecified postsurgical nonabsorption
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antepartum condition or complication
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antepartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
790.2	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry (hyperglycemia)
962.3	Poisoning by insulin and antidiabetic agents
V12.2	Personal history of endocrine, metabolic, and immunity disorders
V58.69	Long-term use of other medication

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical

Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43).

2. Screening is the testing for disease or disease precursors in seemingly well individuals so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no related sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or

exposure to communicable diseases, should be assigned, not a screening code. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52).

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

Medicare National Coverage Decision For Thyroid Testing

Other Names/Abbreviations

Description

Thyroid function studies are used to delineate the presence or absence of hormonal abnormalities of the thyroid and pituitary glands. These abnormalities may be either primary or secondary and often but not always accompany clinically defined signs and symptoms indicative of thyroid dysfunction.

Laboratory evaluation of thyroid function has become more scientifically defined. Tests can be done with increased specificity, thereby reducing the number of tests needed to diagnose and follow treatment of most thyroid disease.

Measurements of serum sensitive thyroid-stimulating hormone (TSH) levels, complemented by determination of thyroid hormone levels [free thyroxine (fT–4) or total thyroxine (T4) with Triiodothyronine (T3) uptake] are used for diagnosis and follow-up of patients with thyroid disorders. Additional tests may be necessary to evaluate certain complex diagnostic problems or on hospitalized patients, where many circumstances can skew tests results. When a test for total thyroxine (total T4 or T4 radioimmunoassay) or T3 uptake is performed, calculation of the free thyroxine index (FTI) is useful to correct for abnormal results for either total T4 or T3 uptake due to protein binding effects.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
84436	Thyroxine; total
84439	Thyroxine; free
84443	Thyroid stimulating hormone (TSH)
84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)

Indications

Thyroid function tests are used to define hyper function, euthyroidism, or hypofunction of thyroid disease. Thyroid testing may be reasonable and necessary to:

- Distinguish between primary and secondary hypothyroidism;
- Confirm or rule out primary hypothyroidism;
- Monitor thyroid hormone levels (for example, patients with goiter, thyroid nodules, or thyroid cancer);
- Monitor drug therapy in patients with primary hypothyroidism;
- Confirm or rule out primary hyperthyroidism; and
- Monitor therapy in patients with hyperthyroidism.

Thyroid function testing may be medically necessary in patients with disease or neoplasm of the thyroid and other endocrine glands. Thyroid function testing may also be medically necessary in patients with metabolic disorders; malnutrition; hyperlipidemia; certain types of anemia; psychosis and non-psychotic personality disorders; unexplained depression; ophthalmologic disorders; various cardiac arrhythmias; disorders of menstruation; skin conditions; myalgias; and a wide array of signs and symptoms, including alterations in consciousness; malaise; hypothermia; symptoms of the nervous and musculoskeletal system; skin and integumentary system; nutrition and metabolism; cardiovascular; and gastrointestinal system. It may be medically necessary to do follow-up thyroid testing in patients with a personal history of malignant neoplasm of the endocrine system and in patients on long-term thyroid drug therapy.

Limitations

Testing may be covered up to two times a year in clinically stable patients; more frequent testing may be reasonable and necessary for patients whose thyroid therapy has been altered or in whom symptoms or signs of hyperthyroidism or hypothyroidism are noted.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
017.50–017.56	Tuberculosis of the thyroid gland
183.0	Malignant neoplasm of ovary
193	Malignant neoplasm of thyroid gland

Code	Description
194.8	Malignant neoplasm of other endocrine glands and related structures, other
198.89	Secondary malignant neoplasm of the thyroid
220	Benign neoplasm of ovary
226	Benign neoplasm of thyroid gland
227.3	Benign neoplasm of pituitary gland and craniopharyngeal duct
234.8	Carcinoma in situ of other and unspecified sites
237.4	Neoplasm of uncertain behavior of other and unspecified endocrine glands
239.7	Neoplasm of unspecified nature, thyroid gland
240.0–240.9	Goiter specified and unspecified
241.0–241.9	Nontoxic nodular goiter
242.00–242.91	Thyrotoxicosis with or without goiter
243	Congenital hypothyroidism
244.0–244.9	Acquired hypothyroidism
245.0–245.9	Thyroiditis
246.0–246.9	Other disorders of thyroid
250.00–250.93	Diabetes mellitus
252.1	Hypoparathyroidism
253.1	Other and unspecified anterior pituitary hyper function
253.2	Panhypopituitarism
253.3–253.4	Pituitary dwarfism
253.4	Other anterior pituitary disorders
253.7	Iatrogenic pituitary disorders
255.2	Adrenogenital disorders
255.4	Corticoadrenal insufficiency
256.3	Ovarian failure
257.2	Testicular hypofunction
258.0–258.9	Polyglandular dysfunction
262	Malnutrition, severe
263.0–263.9	Malnutrition, other and unspecified
266.0	Ariboflavinosis
272.0	Pure hypercholesterolemia
272.2	Mixed hyperlipidemia
272.4	Other and unspecified hyperlipidemia
275.40–275.49	Calcium disorders
276.0	Hyposmolality and/or hypernatremia
276.1	Hyposmolality and/or hyponatremia
278.3	Hypercarotinemia
279.4	Autoimmune disorder, not classified elsewhere
281.0	Pernicious anemia
281.9	Unspecified deficiency anemia
283.0	Autoimmune hemolytic anemia
285.9	Anemia, unspecified
290.0	Senile dementia, uncomplicated
290.10–290.13	Presenile dementia
290.20–290.21	Senile dementia with delusional or depressive features
290.3	Senile dementia with delirium
293.0–293.1	Delirium
293.81–293.89	Transient organic mental disorders
294.8	Other specified organic brain syndromes
296.00–296.99	Affective psychoses
297.0	Paranoid state, simple
297.1	Paranoia
297.9	Unspecified paranoid state
298.3	Acute paranoid reaction
300.00–300.09	Anxiety states
307.9	Agitation—other and unspecified special symptoms or syndromes, not elsewhere classified
310.1	Organic personality syndrome
311	Depressive disorder, not elsewhere classified
331.0–331.2	Alzheimer's, pick's disease, Senile degeneration of brain
333.1	Essential and other specified forms of tremor
333.99	Other extrapyramidao diseases and abnormal movement disorders
354.0	Carpal Tunnel syndrome
356.9	Idiopathic peripheral neuropathy, unspecified polyneuropathy
358.1	Myasthenic syndromes in diseases classified elsewhere
359.5	Myopathy in endocrine diseases classified elsewhere
359.9	Myopathy, unspecified
368.2	Diplopia
372.71	Conjunctival hyperemia
372.73	Conjunctival edema
374.41	Lid retraction or lag
374.82	Eyelid edema
376.21	Thyrotoxic exophthalmos
376.22	Exophthalmic ophthlmoplegia
376.30–376.31	Exophthalmic conditions, unspecified and constant

Code	Description
376.33–376.34	Orbital edema or congestion, intermittent exophthalmos
378.50–378.55	Paralytic strabismus
401.0–401.9	Essential hypertension
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart and renal disease
423.9	Unspecified disease of pericardium
425.7	Nutritional and metabolic cardiomyopathy
427.0	Paroxysmal supraventricular tachycardia
427.2	Paroxysmal tachycardia, unspecified
427.31	Atrial fibrillation
427.89	Other specified cardiac dysrhythmia
427.9	Cardiac dysrhythmia, unspecified
428.0	Congestive heart failure
428.1	Left heart failure
429.3	Cardiomegaly
511.9	Unspecified pleural effusion
518.81	Acute respiratory failure
529.8	Other specified conditions of the tongue
560.1	Paralytic ileus
564.0	Constipation
564.7	Megacolon, other than Hirschsprung's
568.82	Peritoneal effusion (chronic)
625.3	Dysmenorrhea
626.0–626.2	Disorders of menstruation
626.4	Irregular menstrual cycle
648.10–648.14	Other current conditions in the mother, classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium, thyroid dysfunction
676.20–676.24	Engorgement of breast associated with childbirth and disorders of lactation
698.9	Unspecified pruritic disorder
701.1	Keratoderma, acquired (dry skin)
703.8	Other specified diseases of nail (Brittle nails)
704.00–704.09	Alopecia
709.01	Vitiligo
710.0–710.9	Diffuse disease of connective tissue
728.2	Muscle wasting
728.9	Unspecified disorder of muscle, ligament, and fascia
729.1	Myalgia and myositis, unspecified
729.82	Musculoskeletal cramp
730.30–730.39	Periostitis without osteomyelitis
733.09	Osteoporosis, drug induced
750.15	Macroglossia, congenital
759.2	Anomaly of other endocrine glands
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.50–780.52	Insomnia
780.6	Fever
780.71–780.79	Malaise and fatigue
780.8	Hyperhidrosis
780.9	Other general symptoms (hyperthermia)
781.0	Abnormal involuntary movements
781.3	Lack of coordination, ataxia
782.0	Disturbance of skin sensation
782.3	Localized edema
782.8	Changes in skin texture
782.9	Other symptoms involving skin and integumentary tissues
783.1	Abnormal weight gain
783.2	Abnormal loss of weight
783.6	Polyphagia
784.1	Throat pain
784.49	Voice disturbance
784.5	Other speech disturbance
785.0	Tachycardia, unspecified
785.1	Palpitations
785.9	Other symptoms involving cardiovascular system
786.09	Other symptoms involving respiratory system
786.1	Stridor
787.2	Dysphagia
787.91–787.99	Other symptoms involving digestive system
789.5	Ascites
793.9	Nonspecific abnormal findings on radiological and other examination, other (neck)
794.5	Thyroid, abnormal scan or uptake
796.1	Other nonspecific abnormal findings, abnormal reflex
799.2	Nervousness

Code	Description
990	Effects of radiation, unspecified
V10.87	Personal history of malignant neoplasm of the thyroid
V10.88	Personal history of malignant neoplasm of other endocrine gland
V12.2	Personal history of endocrine, metabolic and immunity disorders
V58.69	Long term (current) use of other medications
V67.0-V67.9	Follow-up examination

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for routine screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases

Code	Description
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

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The Merck Manual, 16th Edition, pp. 1072–1081.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

7. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

8. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

9. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

10. Use code 728.9 to report muscle weakness as the indication for the test. Other diagnoses included in 728.9 do not support medical necessity.

11. Use code 194.8 (Malignant neoplasm of other endocrine glands and related structures, Other) to report multiple endocrine neoplasia syndromes (MEN–1 and MEN–2). Other diagnoses included in 194.8 do not support medical necessity.

Documentation Requirements

When these tests are billed at a greater frequency than the norm (two per year), the ordering physician's documentation must support the medical necessity of this frequency.

Medicare National Coverage Decision for Lipids

Other Names/Abbreviations

Description

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise,

genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL–C) and high density lipoprotein cholesterol (HDL–C), are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases.

Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline and high risk categories by the National Heart, Lung and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia (See Reference). Therapy to reduce these risk parameters includes diet, exercise and medication, and fat weight loss, which is particularly powerful when combined with diet and exercise.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
80061	Lipid panel
82465	Cholesterol, serum, total
83715	Lipoprotein, blood; electrophoretic separation and quantitation
83716	Lipoprotein, blood: high resolution fractionation and quantitation of lipoprotein cholesterols (for example, electrophoretic, nuclear magnetic resonance, ultracentrifugation)
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721	Lipoprotein, direct measurement, LDL cholesterol
84478	Triglycerides

Indications

The medical community recognizes lipid testing as appropriate for evaluating atherosclerotic cardiovascular disease. Conditions in which lipid testing may be indicated include:

- Assessment of patients with atherosclerotic cardiovascular disease;
- Evaluation of primary dyslipidemias;
- Any form of atherosclerotic disease;
- Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism;
- Secondary dyslipidemias, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure; and
- Signs or symptoms of dyslipidemias, such as skin lesions.
- As follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200–240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol <35 mg/dl.

To monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if this lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

Electrophoretic or other quantitation of lipoproteins (CPT codes 83715 and 83716) may be indicated if the patient has a primary disorder of lipoid metabolism (ICD–9–CM codes 272.0 to 272.9).

Limitations

Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid estretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.

Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease.

Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for

marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

If no dietary or pharmacological therapy is advised, monitoring is not necessary.

When evaluating non-specific chronic abnormalities of the liver (for example, elevations of transaminase, alkaline phosphatase, abnormal imaging studies, etc.), a lipid panel would generally not be indicated more than twice per year.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–245.9	Disorders of the thyroid gland with hormonal dysfunction
250.00–250.93	Diabetes mellitus
255.0	Cushing's syndrome
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe, protein-calorie malnutrition
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.8	Other protein-calorie malnutrition
263.9	Unspecified protein-calorie malnutrition
270.0	Disturbances of amino-acid transport
271.1	Galactosemia
272.0	Pure hypercholesterolemia
272.1	Hyperglyceridemia
272.2	Mixed hyperlipidemia (tuberous xanthoma)
272.3	Hyperchylomicronemia
272.4	Other and unspecified hyperlipidemia (unspecified xanthoma)
272.5	Lipoprotein deficiencies
272.6	Lipodystrophy
272.7	Lipidoses
272.8	Other disorders of lipoid metabolism
272.9	Unspecified disorders of lipoid metabolism
277.3	Amyloidosis
278.00	Obesity
278.01	Morbid obesity
303.90–303.92	Alcoholism
362.10–362.16	Other background retinopathy and retinal vascular change
362.30–362.34	Retinal vascular occlusion
362.82	Retinal exudates and deposits
371.41	Corneal arcus, juvenile
374.51	Xanthelasma
379.22	Crystalline deposits in vitreous
388.00	Degenerative & vascular disorder of ear, unspecified
388.02	Transient ischemic deafness
401.0, 401.9	Essential hypertension
402.00–402.91	Hypertensive heart disease
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart and renal disease
405.01–405.99	Secondary hypertension
410.00–410.92	Acute myocardial infarction
411.0–411.1	Other acute & subacute forms of ischemic heart disease
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute ischemic heart disease
412	Old myocardial infarction
413.0–413.1	Angina pectoris
413.9	Other and unspecified angina pectoris
414.00–414.03	Coronary atherosclerosis
414.04	Coronary athrscl-artery bypass graft
414.05	Coronary athrscl-unspec graft
414.10	Aneurysm, heart (wall)
414.11	Coronary vessel aneurysm
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
428.0–428.9	Heart failure
429.2	Arteriosclerotic cardiovascular disease
429.9	Heart disease NOS
431	Intracerebral hemorrhage
433.00–433.91	Occlusion & stenosis of precerebral arteries
434.00–434.91	Occlusion of cerebral arteries
435.0–435.9	Transient cerebral ischemia
437.0	Other & ill-defined cerebrovascular disease
437.1	Other generalized ischemic cerebrovascular disease
437.5	Moyamoya disease

Code	Description
438.0–438.9	Late effects of cerebrovascular disease
440.0–440.9	Arteriosclerosis
441.00–441.9	Aortic aneurysms
442.0	Upper extremity aneurysm
442.1	Renal artery aneurysm
442.2	Iliac artery aneurysm
444.0–444.9	Arterial embolism & thrombosis
557.1	Chronic vascular insufficiency of intestine
571.8	Other chronic non-alcoholic liver disease
571.9	Unspecified chronic liver disease without mention of alcohol
573.8	Other specified disorders of liver
573.9	Unspecified disorders of liver
577.0–577.9	Pancreatic disease
579.3	Other & unspecified postsurgical nonabsorption
579.8	Other specified intestinal malabsorption
581.0–581.9	Nephrotic syndrome
584.5	Acute renal failure with lesion of tubular necrosis
585	Chronic renal failure
588.0	Renal osteodystrophy
588.1	Nephrogenic diabetes insipidus
588.8	Other specified disorders resulting from impaired renal function
588.9	Unspecified disorder resulting from impaired renal function
607.84	Impotence of organic origin, penis disorder
646.70–646.71	Liver disorders in pregnancy
646.73	Liver disorder antepartum
648.10–648.14	Thyroid disfunction in pregnancy and the puerperium
696.0	Psoriatic arthropathy
696.1	Other psoriasis
751.61	Biliary atresia
764.10–764.19	''Light for dates'' with signs of fetal malnutrition
786.50	Chest pain unspecified
786.51	Precordial pain
786.59	Chest pain, other
789.1	Hepatomegaly
790.4	Abnormal transaminase
790.5	Abnormal alkaline phosphatase
790.6	Other abnormal blood chemistry
793.4	Abnormal imaging study
987.9	Toxic effect of unspecified gas or vapor
996.81	Complication of transplanted organ, kidney
V42.0	Transplanted organ, kidney
V42.7	Organ replacement by transplant, liver
V58.69	Long term (current) use of other medications

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V.79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it

has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Digoxin Therapeutic Drug Assay

Other Names/Abbreviations

Description

A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
80162	Digoxin (Therapeutic Drug Assay)

Indications

Digoxin levels may be performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow or because the blood level may not be high enough to achieve the desired clinical effect.

Clinical indications may include individuals on digoxin:

- With symptoms, signs or electrocardiogram (ECG) suggestive of digoxin toxicity;
- Taking medications that influence absorption, bioavailability, distribution, and/or elimination of digoxin;
- With impaired renal, hepatic, gastrointestinal, or thyroid function;
- With pH and/or electrolyte abnormalities;
- With unstable cardiovascular status, including myocarditis;
- Requiring monitoring of patient compliance.

Clinical indications may include individuals:

- Suspected of accidental or intended overdose; or
- Who have an acceptable cardiac diagnosis (as listed) and for whom an accurate history of use of digoxin is unobtainable

The value of obtaining regular serum digoxin levels is uncertain, but it may be reasonable to check levels once yearly after a steady state is achieved. In addition, it may be reasonable to check the level if:

- Heart failure status worsens;
- Renal function deteriorates;
- Additional medications are added that could affect the digoxin level; or
- Signs or symptoms of toxicity develop.

Steady state will be reached in approximately 1 week in patients with normal renal function, although 2–3 weeks may be needed in patients with renal impairment. After changes in dosages or the addition of a medication that could affect the digoxin level, it is reasonable to check the digoxin level one week after the change or addition. Based on the clinical situation, in cases of digoxin toxicity, testing may need to be done more than once a week.

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation or flutter. Digoxin may also be indicated for the treatment of other supraventricular arrhythmias, particularly in the presence of heart failure.

Limitations

This test is not appropriate for patients on digitoxin or treated with digoxin FAB (fragment antigen binding) antibody.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
242.00–242.91	Thyrotoxicosis with or without goiter
243	Congenital hypothyroidism
244.0–244.9	Acquired hypothyroidism
245.0–245.9	Thyroiditis
275.2	Disorders of magnesium metabolism
275.40–275.49	Disorders of calcium metabolism
276.0	Hyperosmolality
276.1	Hyposmolality
276.2	Acidosis
276.3	Alkalosis
276.4	Mixed acid-base balance disorder
276.5	Volume depletion
276.6	Fluid Overload
276.7	Hyperpotassemia
276.8	Hypopotassemia
276.9	Electrolyte and fluid Disorder (not elsewhere classified)
293.0	Acute delirium
293.1	Subacute delirium
307.47	Other dysfunctions of sleep stages or arousal from sleep
368.16	Psychophysical visual disturbances
368.8	Other specified visual disturbances
368.9	Unspecified visual disturbances
397.9	Rheumatic diseases of endocardium
398.0	Rheumatic Myocarditis

Code	Description
398.91	Rheumatic Heart Failure
402.01	Hypertensive heart disease, malignant with CHF
402.11	Hypertensive heart disease, benign with CHF
402.91	Hypertensive heart disease, unspecified with CHF
403.00–403.91	Hypertensive renal disease
404.00–404.93	Hypertensive heart & renal disease
410.00–410.92	Acute myocardial infarction
411.0–411.89	Other acute & subacute forms of ischemic heart disease
413.0–413.9	Angina pectoris
422.0–422.99	Acute myocarditis
425.0–425.9	Cardiomyopathy
426.0–426.9	Conduction disorders
427.0–427.9	Cardiac dysrhythmias
428.0–428.9	Heart failure
429.2	Cardiovascular disease, unspecified
429.4	Heart Disturbances Postcardiac Surgery
429.5	Rupture chordae tendinae
429.6	Rupture papillary muscle
429.71	Acquired cardiac septal defect
514	Pulmonary congestion & hypostasis
579.9	Unspecified Intestinal malabsorption
584.5–584.9	Acute renal failure
585	Chronic renal failure
586	Renal Failure, unspecified
587	Renal sclerosis, unspecified
588.0	Renal osteodystrophy
588.1	Nephrogenic Diabetes Insipidus
588.8	Impaired renal function (not elsewhere classified)
588.9	Unspecified disorder resulting from impaired renal function
780.01	Coma
780.02	Transient alteration of awareness
780.09	Other ill-defined general symptoms (drowsiness, semicoma, somnolence, stupor, unconsciousness)
780.1	Hallucinations
780.2	Syncope & collapse
780.4	Dizziness and giddiness
780.71–.79	Malaise & fatigue
783.0	Anorexia
784.0	Headache
787.01–787.03	Nausea & vomiting
787.91	Diarrhea
794.31	Abnormal electrocardiogram
799.2	Nervousness
972.0	Poisoning by cardiac rhythm regulators
972.1	Poisoning by cardiotonic glycosides & drugs of similar action
995.2	Unspecified adverse effect of drug, medicinal and biological substance
*E942.1	Adverse effect of cardiotonic glycosides and drugs of similar action
V58.69	Encounter long term—Medication Use (not elsewhere classified)

*Code may not be reported as a stand-alone or first-listed code on the claim.

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0—V17.8	Family history of certain chronic disabling diseases
V18.0—V18.8	Family history of certain other specific conditions
V19.0—V19.8	Family history of other conditions
V20.0—V20.2	Health supervision of infant or child
V28.0—V28.9	Antenatal screenings
V50.0—V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0—V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0—V68.9	Encounters for administrative purposes
V70.0—V70.9	General medical examinations
V73.0—V73.99	Special screening examinations for viral and chlamydia diseases
V74.0—V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0—V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42—V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0—V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0—V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0—V79.9	Special screening for mental disorders
V80.0—V80.3	Special screening for neurological, eye, and ear diseases
V81.0—V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0—V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom

is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Alpha-fetoprotein
Other Names/Abbreviations: Afp

Description

Alpha-fetoprotein (AFP) is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

HCPCS Codes (alpha numeric CPT © AMA)

Code	Descriptor
82105	Alpha-fetoprotein; serum

Indications

AFP is useful for the diagnosis of hepatocellular carcinoma in high-risk patients (such as alcoholic cirrhosis, cirrhosis of viral etiology, hemochromatosis, and alpha$_1$-antitrypsin deficiency) and in separating patients with benign hepatocellular neoplasms or metastases from those with hepatocellular carcinoma and, as a non-specific tumor associated antigen, serves in marking germ cell neoplasms of the testis, ovary, retro peritoneum, and mediastinum.

Limitations

ICD–9–CM Codes Covered by Medicare Program

Code	Description
070.22–070.23	Chronic viral hepatitis B with hepatic coma, with or without mention of hepatitis delta
070.32–070.33	Chronic viral hepatitis B without mention of hepatic coma, with or without mention of hepatitis delta
070.44	Chronic hepatitis C with hepatic coma
070.54	Chronic hepatitis C without mention of hepatic coma
095.3	Syphilis of liver
121.1	Clonorchiasis
121.3	Fascioliasis
155.0–155.2	Malignant neoplasm of the liver and intrahepatic bile ducts
164.2–164.9	Malignant neoplasm of the mediastinum
183.0	Malignant neoplasm, ovary
186.0	Malignant neoplasm of undescended testis
186.9	Malignant neoplasm, other and unspecific testis
197.1	Secondary malignant neoplasm of mediastinum
197.7	Secondary malignant neoplasm of liver
198.6	Secondary malignant neoplasm of ovary
198.82	Secondary malignant neoplasm, genital organs
211.5	Benign neoplasm of liver and biliary passages
235.3	Neoplasm of uncertain behavior of liver and biliary passages
272.2	Mixed hyperlipidemia
275.0	Disorder of iron metabolites
275.1	Disorder of copper metabolism
277.00	Cystic Fibrosis without mention of meconium ileus
277.6	Other deficiencies of circulating enzymes
285.0	Sideroblastic Anemia
571.2	Alcoholic cirrhosis of liver
571.40	Chronic hepatitis, unspecified
571.41	Chronic persistent hepatitis
571.49	Other chronic hepatitis
571.5	Cirrhosis of liver without mention of alcohol
608.89	Other specified disorders of male genital organs
793.1	Non-specific abnormal findings of lung field
793.2	Non-specific abnormal findings of other intrathoracic organs
793.3	Non-specific abnormal findings of biliary tract
793.6	Non-specific abnormal findings of abdominal area, including retro peritoneum
V10.07	Personal history of malignant neoplasm, liver

Code	Description
V10.43	Personal history of malignant neoplasm, ovary
V10.47	Personal history of malignant neoplasm, testis

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition described by that code must be related to the above indications for the test.

Medicare National Coverage Decision for Carcinoembryonic Antigen

Other Names/Abbreviations: CEA

Description

Carcinoembryonic antigen (CEA) is a protein polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
82378	Carcinoembryonic antigen (CEA)

Indications

CEA may be medically necessary for follow-up of patients with colorectal carcinoma. It would however only be medically necessary at treatment decision-making points. In some clinical situations (e.g. adenocarcinoma of the lung, small cell carcinoma of the lung, and some gastrointestinal carcinomas) when a more specific marker is not expressed by the tumor, CEA may be a medically necessary alternative marker for monitoring. Preoperative CEA may also be helpful in determining the post-operative adequacy of surgical resection and subsequent medical management. In general, a single tumor marker will suffice in following patients with colorectal carcinoma or other malignancies that express such tumor markers.

In following patients who have had treatment for colorectal carcinoma, ASCO guideline suggests that if resection of liver metastasis would be indicated, it is recommended that post-operative CEA testing be performed every two to three months in patients with initial stage II or stage III disease for at least two years after diagnosis.

For patients with metastatic solid tumors which express CEA, CEA may be measured at the start of the treatment and with subsequent treatment cycles to assess the tumor's response to therapy.

Limitations

Serum CEA determinations are generally not indicated more frequently than once per chemotherapy treatment cycle for patients with metastatic solid tumors which express CEA or every two months post-surgical treatment for patients who have had colorectal carcinoma. However, it may be proper to order the test more frequently in certain situations, for example, when there has been a significant change from prior CEA level or a significant change in patient status which could reflect disease progression or recurrence.

Testing with a diagnosis of an in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
150.0–150.9	Malignant neoplasm of the esophagus
151.0–151.9	Malignant neoplasm of stomach
152.0–154.8	Malignant neoplasm of small intestine, including duodenum, rectum, rectosigmoid junction and anus.
157.0–157.9	Primary malignancy of pancreas
159.0	Malignant neoplasm of intestinal tract, part unspecified

Code	Description
162.0–162.9	Malignant neoplasm of trachea, bronchus, lung
174.0–174.9	Malignant neoplasm of female breast
175.0–175.9	Malignant neoplasm of male breast
183.0	Malignant neoplasm of ovary
197.0	Secondary malignant neoplasm of neoplasm of lung
197.4	Secondary malignant neoplasm of small intestine
197.5	Secondary malignant neoplasm of large intestine and rectum
230.3	Carcinoma in situ of colon
230.4	Carcinoma in situ of rectum
230.7	Carcinoma in situ of other/unspecified parts of intestine
230.9	Carcinoma in situ other and unspecified digestive organs
235.2	Neoplasm of uncertain behavior of stomach, intestines, rectum
790.99	Other nonspecific findings on examination of blood
V10.00	Personal history of malignant neoplasm of gastro-intestinal tract, unspecified
V10.3	Personal history of malignant neoplasm, breast
V10.05	Personal history of malignant neoplasm, large intestine
V10.06	Personal history of malignant neoplasm, rectum, rectosigmoid junction, anus
V10.11	Personal history of malignant neoplasm, bronchus, and lung
V10.43	Personal history of malignant neoplasm, ovary
V67.2	Follow-up examination following chemotherapy

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

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- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person

Code	Description
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

Sources of Information

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Vauthey JN. Dudrick PS. Lind DS. Copeland EM 3rd. Management of recurrent colorectal cancer: another look at carcinoembryonic antigen©detected recurrence [see comments]. [Review] Digestive Diseases. 14(1):5–13, 1996 Jan–Feb.

Grem J. The prognostic importance of tumor markers in adenocarcinomas of the gastrointestinal tract. [Review] [38 refs] Current Opinion in Oncology. 9(4):380–7, 1997 Jul.

Bergamaschi R. Arnaud JP. Routine compared with nonscheduled follow-up of patients with ''curative'' surgery for colorectal cancer. Annals of Surgical Oncology. 3(5):464–9, 1996 Sep.

Kim YH. Ajani JA. Ota DM. Lynch P. Roth JA. Value of serial carcinoembryonic antigen levels in patients with resectable adenocarcinoma of the esophagus and stomach Cancer. 75(2):451–6, 1995 Jan 15.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected, ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. To show elevated CEA, use ICD–9–CM 790.99 (Other nonspecific findings on examination of blood) only if a more specific diagnosis has not been made. If a more specific diagnosis has been made, use the code for that diagnosis.

Medicare National Coverage Decision for Human Chorionic Gonadotropin

Other Names/Abbreviations: hCG

Description

Human chorionic gonadotropin.

HCPCS Codes (Alpha numeric, CPT © AMA)

Code	Descriptor
84702	Gonodotropin, chorionic (hCG); quantitative

Indications

hCG is useful for monitoring and diagnosis of germ cell neoplasms of the ovary, testis, mediastinum, retroperitoneum, and central nervous system. In addition, hCG is useful for monitoring pregnant patients with vaginal bleeding, hyperension and/or suspected fetal loss.

Limitations

Not more than once per month for diagnostic purposes. As needed for monitoring of patient progress and treatment. Qualitative hCG assays (CPT

84703) are not appropriate for medically managing patients with known or suspected germ cell neoplasms.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
158.0	Malignant neoplasm of retroperitoneum
158.8	Malignant neoplasm of specified parts of peritoneum
164.2	Malignant neoplasm of anterior mediastinum
164.3	Malignant neoplasm of posterior mediastinum
164.8	Malignant neoplasm, other (includes malignant neoplasm of contiguous overlapping sites of thymus, heart, and mediastinum whose point of origin cannot be determined
164.9	Malignant neoplasm of mediastinum, part unspecified
181	Malignant neoplasm of placenta
183.0	Malignant neoplasm of ovary
183.8	Other specified sites of uterine adnexas
186.0	Malignant neoplasm of undescended testes
186.9	Malignant neoplasm of other and unspecified testis
194.4	Malignant neoplasm of pineal gland
197.1	Secondary malignant neoplasm of mediastinum
197.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
198.6	Secondary malignant neoplasm of ovary
198.82	Secondary malignant neoplasm of other genital organs
236.1	Neoplasm of uncertain behavior, placenta
623.8	Vaginal bleeding
625.9	Pelvic pain
630	Hydatidiform mole
631	Pregnancy, molar
632	Missed abortion
633.9	Ectopic pregnancy
634.00–634.02	Spontaneous abortion, complicated by genital tract and pelvic infection
640.00–640.03	Threatened abortion
642.30–642.34	Transient hypertension of pregnancy
642.40–642.74	Pre-eclampsia or eclampsia
642.90–642.94	Unspecified hypertension complicating pregnancy, childbirth, or the proerperium
V10.09	Personal history of malignant neoplasm, other gastrointestinal sites
V10.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs
V10.43	Personal history of malignant neoplasm, ovary
V10.47	Personal history of malignant neoplasm, testis
V22.0–V22.1	Pregnancy

Reasons for Denial

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- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids

Code	Description
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
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V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay—CA125

Other Names/Abbreviations

Description

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses tumor antigen CA125.

HCPCS Codes (alpha numeric, CPT ©AMA)

Code	Descriptor
86304	Immunoassay for tumor antigen, quantitative, CA 125

Indications

CA 125 is a high molecular weight serum tumor marker elevated in 80% of patients who present with epithelial ovarian carcinoma. It is also elevated in carcinomas of the fallopian tube, endometrium, and endocervix. An elevated level may also be associated with the presence of a malignant mesothelioma.

A CA125 level may be obtained as part of the initial pre-operative work-up for women presenting with a suspicious pelvic mass to be used as a baseline for purposes of post-operative monitoring. Initial declines in CA 125 after initial surgery and/or chemotherapy for ovarian carcinoma are also measured by obtaining three serum levels during the first month post treatment to determine the patient's CA 125 half-life, which has significant prognostic implications.

CA 125 levels are again obtained at the completion of chemotherapy as an index of residual disease. Surveillance CA–125 measurements are generally obtained every 3 months for 2 years, every 6 months for the next 3 years, and yearly thereafter. CA 125 levels are also an important indicator of a patient's response to therapy in the presence of advanced or recurrent disease. In this setting, CA 125 levels may be obtained prior to each treatment cycle.

Limitations

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

CA 125 is specifically not covered for aiding in the differential diagnosis of patients with a pelvic mass as the sensitivity and specificity of the test is not sufficient. In general, a single ''tumor marker'' will suffice in following a patient with one of these malignancies.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
180.0	Malignant neoplasm, endocervix
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm,ovary
183.2	Malignant neoplasm, fallopian tube
183.8	Malignant neoplasm, other specified sites of uterine adnexa
184.8	Malignant neoplasm, other specified sites of female genital organs
198.6	Secondary malignant neoplasm, ovary
198.82	Secondary malignancy of genital organs
236.0–236.3	Neoplasm of uncertain behavior of female genital organs
V10.43–V10.44	Personal history of malignant neoplasm of female genital organs

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
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- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
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- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, et al. Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Documentation Requirements

Indicated if service request for CA125 is requested more frequently than stipulated.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA 15–3/CA 27.29

Other Names/Abbreviations

Description

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses the following tumor antigens: CA 15–3 and CA 27.29

HCPCS Codes (Alpha Numeric, CPT–AMA)

Code	Descriptor
86300	Immunoassay for tumor antigen, quantitative; CA 15–3 (27.29)

Indications

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy. CA 15–3 is often medically necessary to aid in the management of patients with breast cancer. Serial testing must be used in conjunction with other clinical methods for monitoring breast cancer. For monitoring, if medically necessary, use consistently either CA 15–3 or CA 27.29, not both. CA 27.29 is equivalent to CA 15–3 in its usage in management of patients with breast cancer.

Limitations

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
174.0–174.9	Breast, primary (female)—malignant neoplasm of female breast
175.0–175.9	Breast, primary (male)—malignant neoplasm of male breast
198.2	Secondary malignant neoplasm (male breast)
198.81	Secondary malignant neoplasm (female breast)
V10.3	Personal history of malignant neoplasm, breast

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemi
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms

Code	Description
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0—V17.8	Family history of certain chronic disabling diseases
V18.0—V18.8	Family history of certain other specific conditions
V19.0—V19.8	Family history of other conditions
V20.0—V20.2	Health supervision of infant or child
V28.0—V28.9	Antenatal screenings
V50.0—V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0—V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0—V68.9	Encounters for administrative purposes
V70.0—V70.9	General medical examinations
V73.0—V73.99	Special screening examinations for viral and chlamydia diseases
V74.0—V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0—V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42—V76.9	Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum)
V77.0—V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0—V78.9	Special Screening for disorders of blood and blood-forming organs
V79.0—V79.9	Special screening for mental disorders
V80.0—V80.3	Special screening for neurological, eye, and ear diseases
V81.0—V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0—V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, et al. Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

Bone GG, von Mensdorff-Pouilly S, Kenemans P, van Kamp GJ, et al. Clinical and Technical Evaluation of ACS BR Serum Assay of MUC–1 Gene Derived Glycoprotein in Breast Cancer, and Compared with CA15–3 Assays. Clin Chem 1997, 43(4):585–593.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA 19–9

Other Names/Abbreviations:

Description

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses the following tumor antigen: CA19–9.

HCPCS Codes (Alpha Numeric, CPT © AMA)

Code	Descriptor
86301	Immunoassay for tumor antigen, quantitative; CA 19–9

Indications

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy. Levels are useful in following the course of patients with established diagnosis of pancreatic and biliary ductal carcinoma. The test is not indicated for diagnosing these two diseases.

Limitations

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
155.1	Malignant neoplasm, intrahepatic bile ducts
156.1	Malignant neoplasm, extrahepatic bile ducts
156.8	Malignant neoplasm, other specified sites of gallbladder and extrahepatic bile ducts
156.9	Malignant neoplasm, unspecified part of biliary tract
157.0–157.9	Malignant neoplasm, pancreas
197.8	Secondary malignant neoplasm, other digestive organs and spleen
235.3	Neoplasm of uncertain behavior, liver and biliary passages
235.5	Neoplasm of uncertain behavior, other and unspecified digestive organs
V10.09	Other personal history of cancer

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0—798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions

Code	Description
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydia diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Richter JM, Christensen MR, Rustgi AK, and Silverstein MD. The Clinical Utility of the CA19–9 Radioimmunoassay for the Diagnosis of Pancreatic Cancer Presenting as Pain or Weight Loss: A Cost Effective Analysis. Arch Intern Med 1989, 149:2292–2297.

Safi F, SchlosseW, Falkenreck S, et. al. Prognostic Value of CA 19–9 Serum Course in Pancreatic Cancer. Hepaetogastroenterology 1998 Jan–Feb; 45(19):253–9.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Prostate Specific Antigen

Other Names/Abbreviations: Total PSA

Description

PSA, a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to six months after radical prostatectomy, PSA is reported to provide a sensitive indicator of persistent disease. Six months following introduction of antiandrogen therapy, PSA is reported as capable of distinguishing patients with favorable response from those in whom limited response is anticipated. PSA when used in conjunction with other prostate cancer tests, such as digital rectal examination, may assist in the decision making process for diagnosing prostate cancer. PSA also, serves as a marker in following the progress of most prostate tumors once a diagnosis has been established. This test is also an aid in the management of prostate cancer patients and in detecting metastatic or persistent disease in patients following treatment.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
84153	Prostate Specific Antigen (PSA), total

Indications

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder. PSA is also a marker used to follow the progress of prostate cancer once a diagnosis has been established, such as in detecting metastatic or persistent disease in patients who may require additional treatment. PSA testing may also be useful in the differential diagnosis of men presenting with as yet undiagnosed disseminated metastatic disease.

Limitations

Generally, for patients with lower urinary tract signs or symptoms, the test is performed only once per year unless there is a change in the patient's medical condition. Testing with a diagnosis of in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
185	Malignant neoplasm of prostate
188.5	Malignant neoplasm of bladder neck
196.5	Secondary malignant neoplasm, lymph nodes inguinal region and lower limb
196.6	Secondary malignant neoplasm, intrapelvic lymph nodes
196.8	Secondary malignant neoplasm, lymph nodes of multiple sites
198.5	Secondary malignant neoplasm, bone and bone marrow
198.82	Secondary malignant neoplasm, genital organs
233.4	Carcinoma in situ, prostate
236.5	Neoplasm of uncertain behavior of prostate
239.5	Neoplasm of unspecified nature, other genitourinary organs
596.0	Bladder neck obstruction
599.6	Urinary obstruction, unspecified
599.7	Hematuria
601.9	Unspecified prostatitis
602.9	Unspecified disorder of prostate
788.20	Retention of urine, unspecified
788.21	Incomplete bladder emptying
788.30	Urinary incontinence, unspecified
788.41	Urinary frequency
788.43	Nocturia
788.62	Slowing of urinary stream
790.93	Elevated prostate specific antigen
793.6/793.7	Non-specific abnormal result of radiologic examination, evidence of malignancy
794.9	Bone scan evidence of malignancy
V10.46	Personal history of malignant neoplasm; prostate

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Laboratory Test Handbook, 3rd edition, pp. 338–340.

Cooner WH, Mosley BR, Rutherford CL, et al. Prostate Cancer Detection in a Clinical Urological Practice by Ultrasonography, Digital Rectal Examination and Prostate Specific Antigen. J.Urol.1990;143: 1146–1154.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign,

symptom or condition must be related to the indications for the test above.

6. To show elevated PSA, use ICD–9–CM code 790.93 (Elevated prostate specific antigen). If a more specific diagnosis code has been made, use the code for that diagnosis.

Medicare National Coverage Decision for Gamma Glutamyl Transferase

Other Names/Abbreviations: GGT

Description

Gamma glutamyltransferase (GGT) is an intracellular enzyme that appears in blood following leakage from cells. Renal tubules, liver, and pancreas contain high amounts, although the measurement of GGT in serum is almost always used for assessment of hepatobiliary function. Unlike other enzymes which are found in heart, skeletal muscle, and intestinal mucosa as well as liver, the appearance of an elevated level of GGT in serum is almost always the result of liver disease or injury. It is specifically useful to differentiate elevated alkaline phosphatase levels when the source of the alkaline phosphatase increase (bone, liver, or placenta) is unclear. The combination of high alkaline phosphatase and a normal GGT does not, however, rule out liver disease completely.

As well as being a very specific marker of hepatobiliary function, GGT is also a very sensitive marker for hepatocellular damage. Abnormal concentrations typically appear before elevations of other liver enzymes or bilirubin are evident. Obstruction of the biliary tract, viral infection (e.g., hepatitis, mononucleosis), metastatic cancer, exposure to hepatotoxins (e.g., organic solvents, drugs, alcohol), and use of drugs that induce microsomal enzymes in the liver (e.g., cimetidine, barbiturates, phenytoin, and carbamazepine) all can cause a moderate to marked increase in GGT serum concentration. In addition, some drugs can cause or exacerbate liver dysfunction (e.g., atorvastatin, troglitazone, and others as noted in FDA Contraindications and Warnings.)

GGT is useful for diagnosis of liver disease or injury, exclusion of hepatobiliary involvement related to other diseases, and patient management during the resolution of existing disease or following injury.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82977	Glutamyltransferase, gamma (GGT)

Indications

1. To provide information about known or suspected hepatobiliary disease, for example:
a. following chronic alcohol or drug ingestion;
b. following exposure to hepatotoxins;
c. when using medication known to have a potential for causing liver toxicity (e.g., following the drug manufacturer's recommendations); or
d. following infection (e.g., viral hepatitis and other specific infections such as amebiasis, tuberculosis, psittacosis, and similar infections)
2. To assess liver injury/function following diagnosis of primary or secondary malignant neoplasms
3. To assess liver injury/function in a wide variety of disorders and diseases known to cause liver involvement (e.g., diabetes mellitus, malnutrition, disorders of iron and mineral metabolism, sarcoidosis, amyloidosis, lupus, and hypertension)
4. To assess liver function related to gastrointestinal disease
5. To assess liver function related to pancreatic disease
6. To assess liver function in patients subsequent to liver transplantation
7. To differentiate between the different sources of elevated alkaline phosphatase activity

Limitations

When used to assess liver dysfunction secondary to existing non-hepatobiliary disease with no change in signs, symptoms, or treatment, it is generally not necessary to repeat a GGT determination after a normal result has been obtained unless new indications are present.

If the GGT is the only ''liver'' enzyme abnormally high, it is generally not necessary to pursue further evaluation for liver disease for this specific indication.

When used to determine if other abnormal enzyme tests reflect liver abnormality rather than other tissue, it generally is not necessary to repeat a GGT more than one time per week. Because of the extreme sensitivity of GGT as a marker for cytochrome oxidase induction or cell membrane permeability, it is generally not useful in monitoring patients with known liver disease.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
003.1	Salmonella septicemia
006.0–006.9	Amebiasis
014.00–014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
017.90–017.96	Tuberculosis of other specified organs
018.90–018.96	Miliary tuberculosis, unspecified
020.0–020.9	Plague
022.3	Anthrax septicemia
027.0	Listeriosis
027.1	Erysipelothrix infection
030.1	Tuberculoid leprosy [Type T]
032.83	Diphtheritic peritonitis
036.1	Meningococcal encephalitis
036.2	Meningococcemia
038.0–038.9	Septicemia
039.2	Actinomycotic infections, abdominal
040.0	Gas gangrene

Code	Description
042	Human immunodeficiency virus (HIV) disease
054.0	Eczema herpeticum
054.5	Herpetic septicemia
060.0–060.1	Yellow fever
070.0–070.9	Viral hepatitis
072.71	Mumps hepatitis
073.0	Ornithosis, with pneumonia
074.8	Other specified diseases due to Coxsackie virus
075	Infectious mononucleosis
078.5	Cytomegaloviral disease
079.99	Unspecified viral infection
082.0–082.9	Tick-borne rickettsioses, stet
084.9	Other pernicious complications of malaria
086.1	Chagas disease with organ involvement other than heart
088.81	Lyme disease
091.62	Secondary syphilitic hepatitis
095.3	Syphilis of liver
100.0	Leptospirosis icterohemorrhagica
112.5	Candidiasis, disseminated
115.00	Infection by Histoplasma capsulatum without mention of manifestation
120.9	Schistosomiasis, unspecified
121.1	Clonorchiasis
121.3	Fascioliasis
122.0	Echinococcus granulosus infection of liver
122.5	Echinococcus multilocularis infection of liver
122.8	Echinococcosis, unspecified, of liver
122.9	Echinococcus, other and unspecified
130.5	Hepatitis due to toxoplasmosis
135	Sarcoidosis
150.0–159.9	Malignant neoplasm of digestive organs and peritoneum
160.0–165.9	Malignant neoplasm of respiratory and intrathoracic organs
170.0–176.9	Malignant neoplasm of bone, connective tissue, skin, and breast
179–189.9	Malignant neoplasm of genitourinary organs
200.00–208.91	Malignant neoplasm of lymphatic and hematopoietic tissue
211.5	Benign neoplasm of liver and biliary passages
211.6	Benign neoplasm of pancreas, except islets of Langerhans
211.7	Benign neoplasm of islets of Langerhans
228.04	Hemangioma of intra-abdominal structures
230.7	Carcinoma in situ of other and unspecified parts of intestine
230.8	Carcinoma in situ of liver and biliary system
230.9	Carcinoma in situ other and unspecified digestive organs
235.0–238.9	Neoplasms of uncertain behavior
239.0	Neoplasm of unspecified nature of digestive system
250.00–250.93	Diabetes mellitus
252.0	Hyperparathyroidism
263.1	Malnutrition of mild degree
263.9	Unspecified protein-calorie malnutrition
268.0	Rickets, active
268.2	Osteomalacia, unspecified
269.0	Deficiency of vitamin K
270.2	Other disturbances of aromatic amino acid metabolism
270.9	Unspecified disorder of amino acid metabolism
271.0	Glycogenosis
272.0	Pure hypercholesterolemia
272.1	Pure hyperglyceridemia
272.2	Mixed hyperlipidemia
272.4	Other and unspecified hyperlipidemia
272.7	Lipidoses
272.9	Unspecified disorder of lipoid metabolism
275.0	Disorders of iron metabolism
275.1	Disorders of copper metabolism
275.3	Disorders of phosphorus metabolism
275.40–275.49	Disorders of calcium metabolism
277.1	Disorders of porphyrin metabolism
277.3	Amyloidosis
277.4	Disorders of bilirubin excretion
277.6	Other deficiencies of circulating enzymes
282.60–282.69	Sickle cell anemia
286.6	Defibrination syndrome
286.7	Acquired coagulation factor deficiency
289.4	Hypersplenism
291.0–291.9	Alcoholic psychoses
303.00–303.03	Acute alcoholic intoxication
303.90–303.93	Other and unspecified alcohol dependence

Code	Description
304.0–304.9	Drug dependence
305.00–305.93	Non-dependent abuse of drugs
357.5	Alcoholic polyneuropathy
359.2	Myotonic disorders
452	Portal vein thrombosis
453.0–453.9	Other vein embolism and thrombosis
456.0–456.21	Esophageal varices
555.0–555.9	Regional enteritis
556.0–556.9	Ulcerative colitis
557.0	Acute vascular insufficiency of intestine
558.1–558.9	Other noninfectious gastroenteritis and colitis
560.0–560.9	Intestinal obstruction without mention of hernia
562.01	Diverticulitis of small intestine (without mention of hemorrhage)
562.03	Diverticulitis of small intestine with hemorrhage
562.11	Diverticulitis of colon (without mention of hemorrhage)
562.13	Diverticulitis of colon with hemorrhage
567.0–567.9	Peritonitis
569.83	Perforation of intestine
570	Acute and subacute necrosis of liver
571.0–571.9	Chronic liver disease and cirrhosis
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.0–573.9	Other disorders of liver
574.00–574.91	Cholelithiasis
575.0–575.9	Other disorders of gallbladder
576.0–576.9	Other disorders of biliary tract
581.0–581.9	Nephrotic syndrome
582.0–582.9	Chronic glomerulonephritis
583.0–583.9	Nephritis and nephropathy not specified as acute or chronic
584.5–584.9	Acute renal failure
585	Chronic renal failure
586	Renal failure, unspecified
587	Renal sclerosis, unspecified
588.0–588.9	Disorders resulting from impaired renal function
590.00–590.9	Infections of kidney
642.5	Severe pre-eclampsia
646.7	Liver disorders in pregnancy
782.4	Jaundice, unspecified, not of newborn
789.1	Hepatomegaly
790.4	Nonspecific elevation of levels of transaminase or lactic acid dehydrgenase
790.5	Other nonspecific abnormal serum enzyme levels
960.0–979.9	Poisoning by drugs, medicinal, and biological substances
980.0–989.89	Toxic effects of substances chiefly nonmedical as to source
V42.7	Organ replaced by transplant, liver
V58.61–V58.69	Long term (current) drug use
V67.1	Follow-up examination, radiotherapy
V67.2	Follow-up examination, chemotherapy
V67.51	Follow-up examination after completed treatment with high-risk medications, not elsewhere classified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing

performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

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Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed

when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Hepatitis Panel

Description

This panel consists of the following tests:

Hepatitis B surface antigen (HBsAg) (CPT 87340)
Hepatitis C antibody (CPT 86803)
Hepatitis B core antibody (HBcAb), IgM Antibody (CPT 86705)
Hepatitis A antibody (HAAb), IgM Antibody (CPT 86709)

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated Hepatitis A, B, C, D, and E. Most cases are caused by Hepatitis A virus (HAV), Hepatitis B virus (HBV), or Hepatitis C virus (HCV).

HAV is the most common cause of hepatitis in children and adolescents in the United States. Prior exposure is indicated by a positive IgG anti-HAV. Acute HAV is diagnosed by IgM anti-HAV, which typically appears within four weeks of exposure, and which disappears within three months of its appearance. IgG anti-HAV is similar in the timing of its appearance, but it persists indefinitely. Its detection indicates prior effective immunization or recovery from infection. Although HAV is spread most commonly by fecal-oral exposure, parenteral infection is possible during the acute viremia stage of the disease. After exposure, standard immune globulin may be effective as a prophylaxis.

HBV produces three separate antigens (surface, core, and e (envelope) antigens) when it infects the liver, although only hepatitis B surface antigen (HBsAg) is included as part of this panel. Following exposure, the body normally responds by producing antibodies to each of these antigens; one of which is included in this panel: hepatitis B surface antibody (HBsAb)-IgM antibody , HBsAg is the earlier marker, appearing in serum four to eight weeks after exposure, and typically disappearing within six months after its appearance. If HBsAg remains detectable for greater than six months, this indicates chronic HBV infection. HBcAb, in the form of both IgG and IgM antibodies, are next to appear in serum, typically becoming detectable two to three months following exposure. The IgM antibody gradually declines or disappears entirely one to two years following exposure, but the IgG usually remains detectable for life. Because HBsAg is present for a relatively short period and usually displays a low titer, a negative result does not exclude an HBV diagnosis. HBcAb, on the other hand, rises to a much higher titer and remains elevated for a longer period of time, but a positive result is not diagnostic of acute disease, since it may be the result of a prior infection. The last marker to appear in the course of a typical infection is HBsAb, which appears in serum four to six months following exposure, remains positive indefinitely, and confers immunity. HBV is spread exclusively by exposure to infected blood or body fluids; in the U.S., sexual transmission accounts for 30% to 60% of new cases of HBV infection.

The diagnosis of acute HBV infection is best established by documentation of a positive IgM antibody against the core antigen (HBcAb-IgM) and by identification of a positive hepatitis B surface antigen (HBsAg). The diagnosis of chronic HBV infection is established primarily by identifying a positive hepatitis B surface antigen (HBsAg) and demonstrating positive IgG antibody directed against the core antigen (HBcAb-IgG). Additional tests such as Hepatitis B e antigen (HBeAg) and Hepatitis B e antibody (HBeAb), the envelope antigen and antibody, are not included in the Hepatitis Panel, but may be of importance in assessing the infectivity of patients with HBV. Following completion of a HBV vaccination series, HBsAb alone may be used monthly for up to six months, or until a positive result is obtained, to verify an adequate antibody response. HCV is the most common cause of post-transfusion hepatitis; overall HCV is 0responsible for 15% to 20% of all cases of acute hepatitis, and is the most common cause of chronic liver disease. The test most commonly used to identify HCV measures HCV antibodies, which appear in blood two to four months after infection. False positive HCV results can occur. For example, a patient with a recent yeast infection may produce a false positive anti-HCV result. For this reason, at present positive results usually are confirmed by a more specific technique. Like HBV, HCV is spread exclusively through exposure to infected blood or body fluids.

This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease of injury. When the time of exposure or the stage of the disease is not known, a patient with continued symptoms of liver disease despite a completely negative Hepatitis Panel may need a repeat panel approximately two weeks to two months later to exclude the possibility of hepatitis. Once a diagnosis is established, specific tests can be used to monitor the course of the disease.

HCPCS Codes (Alpha Numeric, CPT © AMA)

Code	Descriptor
80074	Acute Hepatitis Panel

Indications

1. To detect viral hepatitis infection when there are abnormal liver function test results, with or without signs or symptoms of hepatitis.

2. Prior to and subsequent to liver transplantation.

Limitations

After a hepatitis diagnosis has been established, only individual tests, rather than the entire panel, are needed.

ICD–9–CM Codes Covered by Medicare Program

Code	Description
070.0–070.9	Viral hepatitis
456.0–456.21	Esophageal varices with or without mention of bleeding
570	Acute and subacute necrosis of liver
571.5	Cirrhosis of liver without mention of alcohol
572.0–572.8	Liver abscess and sequelae of chronic liver disease
573.3	Hepatitis, unspecified
780.31	Febrile convulsions
780.71	Chronic fatigue syndrome
780.79	Other malaise and fatigue
782.4	Jaundice, unspecified, not of newborn
783.0–783.6	Symptoms concerning nutrition, metabolism, and development
784.69	Other symbolic dysfunction
787.01–787.03	Nausea and vomiting
789.00–789.09	Abdominal pain
789.1	Hepatomegaly
789.6	Localized abdominal tenderness (RUQ)
794.8	Nonspecific abnormal results of function
999.3	Other infection following infusion
996.82	Complications of transplanted organ, liver
V72.85	Liver transplant recipient evaluation

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs

Code	Description
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

Sources of Information

Ockner, R.K., ''Approaches to the diagnosis of jaundice,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 817–818.

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Illustrated Guide to Diagnostic Tests (2nd ed.), 1997, Springhouse Corporation.

Sleisenger and Fordtrans's Gastrointestinal and Liver Disease (6th ed.), 1997, W.B. Saunders.

Coding Guidelines

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of

certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

Medicare National Coverage Decision for Fecal Occult Blood

Description:

The fecal occult blood test detects the presence of trace amounts of blood in stool. The procedure is performed by testing one or several small samples of one, two or three different stool specimens.

This test may be performed with or without evidence of iron deficiency anemia, which may be related to gastrointestinal blood loss. The range of causes for blood loss include inflammatory causes, including acid-peptic disease, non-steroidal anti-inflammatory drug use, hiatal hernia, Crohn's disease, ulcerative colitis, gastroenteritis, and colon ulcers. It is also seen with infectious causes, including hookworm, stronglyoidal ascariasis, tuberculosis, and enteroamebiasis. Vascular causes include angiodysplasia, hemangiomas, varices, blue rubber bleb nevus syndrome, and watermelon stomach. Tumors and neoplastic causes include lymphoma, leiomyosarcoma, lipomas, adenocarcinoma and primary and secondary metastases to the GI tract. Drugs such as nonsteroidal anti-inflammatory drugs also cause bleeding. There are extra gastrointestinal causes such as hemoptysis, epistaxis, and oropharyngeal bleeding. Artifactual causes include hematuria, and menstrual bleeding. In addition, there may be other causes such as coagulopathies, gastrostomy tubes or other appliances, factitial causes, and long distance running.

Three basic types of fecal hemoglobin assays exist, each directed at a different component of the hemoglobin molecule.

(1) Immunoassays recognize antigenic sites on the globin portion and are least affected by diet or proximal gut bleeding, but the antigen may be destroyed by fecal flora.

(2) The heme-porphyrin assay measures heme-derived porphyrin and is least influenced by enterocolic metabolism or fecal storage. This assay does not discriminate dietary from endogenous heme. The capacity to detect proximal gut bleeding reduces its specificity for colorectal cancer screening but makes it more useful for evaluating overall GI bleeding in case finding for iron deficiency anemia.

(3) The guaiac-based test is the most widely used. It requires the peroxidase activity of an intact heme moiety to be reactive. Positivity rates fall with storage. Fecal hydration such as adding a drop of water increases the test reactivity but also increases false positivity.

Of these three tests, the guaiac-based test is the most sensitive for detecting lower bowel bleeding. Because of this sensitivity, it is advisable, when it is used for screening, to defer the guaiac-based test if other studies of the colon are performed prior to the test. Similarly, this test's sensitivity may result in a false positive if the patient has recently ingested meat. Both of these cautions are appropriate when the test is used for screening, but when appropriate indications are present, the test should be done despite its limitations.

HCPCS Codes (alpha numeric, CPT © AMA)

Code	Descriptor
82270	Blood, occult; feces, 1–3 simultaneous determinations

Indications

1. To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract.

2. To evaluate unexpected anemia.

3. To evaluate abnormal signs, symptoms, or complaints that might be associated with loss of blood.

4. To evaluate patient complaints of black or red-tinged stools.

Limitations

1. Code 82270 is reported once for the testing of up to three separate specimens (comprising either one or two tests per specimen).

2. In patients who are taking non-steroidal anti-inflammatory drugs and have a history of gastrointestinal bleeding but no other signs, symptoms, or complaints associated with gastrointestinal blood loss, testing for occult blood may generally be appropriate no more than once every three months.

3. When testing is done for the purpose of screening for colorectal cancer in the absence of signs, symptoms, conditions, or complaints associated with gastrointestinal blood loss, HCPCS code G0107 (Colorectal cancer screening; fecal-occult blood test, 1–3 simultaneous determinations) should be used. Coverage of colorectal cancer screening is described in HCFA Program Memorandum Transmittal No. AB–97–24 (November, 1997).

ICD–9–CM Codes Covered by Medicare Program

Code	Description
003.0	Salmonella gastroenteritis
003.1	Salmonella septicemia
004.0–004.9	Shigellosis
005.0–005.9	Other food poisoning (bacterial)
006.0–006.9	Amebiasis
007.0–007.9	Other protozoal intestinal diseases
008.41–008.49	Intestinal infections due to other specified bacteria
009.0–009.3	Ill defined intestinal infections
014.00–014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands
040.2	Whipple's disease
095.2	Syphilitic peritonitis

Code	Description
095.3	Syphilis of liver
098.0	Gonococcal infections, acute, lower enitourinary tract
098.7	Gonococcal infection anus and rectum
098.84	Gonococcal endocaritis
123.0–123.9	Other cestode infection
124	Trichinosis
127.0–127.9	Other intestinal helminthiases
139.8	Late effects of other and unspecified infectious and parasitic diseases
150.0–157.9	Malignant neoplasm of digestive organisms
159.0—0.159.9	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
176.3	Kaposi's sarcoma, gastrointestinal sites
197.4–197.5	Secondary malignant neoplasm of intestines
197.8	Secondary malignant neoplasm of other digestive organs and spleen
199.0	Disseminated malignant neoplasm
204.00–204.91	Lymphoid leukemia
205.00–208.91	Leukemia
211.0–211.9	Benign neoplasm of other parts of digestive system
228.04	Hemangioma of intra-abdominal structures
230.2–230.9	Carcinoma in situ of digestive organs
235.2	Neoplasm of uncertain behavior of stomach, intestines, and rectum
235.5	Neoplasm of uncertain behavior of other and unspecified digestive organs
239.0	Neoplasm of unspecified nature, digestive system
280.0–280.9	Iron deficiency anemias
285.0–285.9	Other and unspecified anemias
286.0–286.9	Coagulation defects
287.0–287.9	Purpura and other hemorrhagic conditions
448.0	Hereditary hemorrhagic telangiectasia
455.0–455.8	Hemorrhoids
456.0–456.21	Esophageal varices with or without mention of bleeding
530.10–535.61	Diseases of the esophagus, stomach, and duodenum
536.2	Persistent vomiting
536.8–536.9	Dyspepsia and other specified and unspecified functional disorders of the stomach
537.0–537.4	Other disorders of stomach and duodenum
537.82–537.83	Angiodysplasia of stomach and duodenum
537.89	Other specified disorders of stomach and duodenum
555.0–558.9	Non-infectious enteritis and colitis
560.0–560.39	Intestinal obstruction/impaction without mention of hernia
562.10–562.13	Diverticulosis/diverticulitis of colon
564.0–564.9	Functional digestive disorders, not elsewhere classified
565.0–565.1	Anal fissure and fistula
569.0	Anal and rectal polyp
569.1	Rectal prolapse
569.3	Hemorrhage of rectum and anus
569.41–569.49	Other specified disorders of rectum and anus
569.82–569.83	Ulceration and perforation of intestine
569.84–569.85	Angiodysplasia of intestine with or without mention of hemorrhage
571.0–571.9	Chronic liver disease and cirrhosis
577.0	Acute pancreatitis
577.0–577.9	Diseases of the pancreas
578.0–578.9	Gastrointestinal hemorrhage
579.0	Celiac disease
579.8	Other specified intestinal malabsorption
596.1	Intestinovesical fistula
617.5	Endometriosis of intestine
780.71	Chronic fatigue syndrome
780.79	Other malaise and fatigue
783.0	Anorexia
783.2	Abnormal loss of weight
787.01–787.03	Nausea and vomiting
787.1	Heartburn
787.2	Dysphagia
787.7	Abnormal feces
787.91	Diarrhea
787.99	Other symptoms involving digestive system
789.00–789.09	Abdominal pain
789.30–789.39	Abdominal or pelvic swelling, mass, or lump
789.40–789.49	Abdominal rigidity
789.5	Ascites
789.60–789.69	Abdominal tenderness
790.92	Abnormal coagulation profile
792.1	Nonspecific abnormal findings in stool contents
793.6	Nonspecific abnormal findings on radiological and other examination, abdominal area, including retroperitoneum
794.8	Nonspecific abnormal results of function studies, liver

Code	Description
863.0–863.90	Injury to gastrointestinal tract
864.00–864.09	Injury to liver without mention of open wound into cavity
864.11–864.19	Injury to liver with open wound into cavity
866.00–866.03	Injury to kidney without mention of open wound into cavity
866.10–866.13	Injury to kidney with open wound into cavity
902.0–902.9	Injury to blood vessels of abdomen and pelvis
926.11–926.19	Crushing injury of trunk, other specified sites
926.8	Crushing injury of trunk, multiple sites
926.9	Crushing injury of trunk, unspecified site
964.2	Poisoning by agents primarily affecting blood constituents, anticoagulants
995.2	Unspecified adverse effect of drug, medicinal, and biological substance
V10.00–.09	Personal history of malignant neoplasm, gastrointestinal tract
V12.00	Personal history of unspecified infectious and parasitic disease
V12.72	Personal history of colonic polyps
V58.61	Long term (current) use of anticoagulants
V58.69	Long term (current) use of other medications
V67.51	Following treatment with high risk medication, not elsewhere specified

Reasons for Denial

Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

ICD–9–CM Codes Denied

Code	Description
798.0–798.9	Sudden death, cause unknown
V15.85	Exposure to potentially hazardous body fluids
V16.1	Family history of malignant neoplasm, trachea, bronchus, and lung
V16.2	Family history of malignant neoplasm, other respiratory and intrathoracic organs
V16.4	Family history of malignant neoplasm, genital organs
V16.5	Family history of malignant neoplasm, urinary organs
V16.6	Family history of malignant neoplasm, leukemia
V16.7	Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms
V16.8	Family history of malignant neoplasm, other specified malignant neoplasm
V16.9	Family history of malignant neoplasm, unspecified malignant neoplasm
V17.0–V17.8	Family history of certain chronic disabling diseases
V18.0–V18.8	Family history of certain other specific conditions
V19.0–V19.8	Family history of other conditions
V20.0–V20.2	Health supervision of infant or child
V28.0–V28.9	Antenatal screenings
V50.0–V50.9	Elective surgery for purposes other than remedying health states
V53.2	Fitting and adjustment of hearing aid
V60.0–V60.9	Housing, household, and economic circumstances
V62.0	Unemployment
V62.1	Adverse effects of work environment
V65.0	Healthy persons accompanying sick persons
V65.1	Persons consulting on behalf of another person
V68.0–V68.9	Encounters for administrative purposes
V70.0–V70.9	General medical examinations
V73.0–V73.99	Special screening examinations for viral and chlamydial diseases

Code	Description
V74.0–V74.9	Special screening examinations for bacterial and spirochetal diseases
V75.0–V75.9	Special screening examination for other infectious diseases
V76.0	Special screening for malignant neoplasms, respiratory organs
V76.3	Special screening for malignant neoplasms, bladder
V76.42–V76.9	Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum)
V77.0–V77.9	Special screening for endocrine, nutrition, metabolic, and immunity disorders
V78.0–V78.9	Special screening for disorders of blood and blood-forming organs
V79.0–V79.9	Special screening for mental disorders
V80.0–V80.3	Special screening for neurological, eye, and ear diseases
V81.0–V81.6	Special screening for cardiovascular, respiratory, and genitourinary diseases
V82.0–V82.9	Special screening for other conditions

ICD–9–CM Codes That Do Not Support Medical Necessity

Any ICD–9–CM code not listed in either of the ICD–9-CM sections above.

Sources of Information

Ahlquist, D.A., ''Approach to the patient with occult gastrointestinal bleeding,'' in Tadatake, Y. (ed.), *Textbook of Gastroenterology* (2nd ed.), 1995, J.B. Lippincott, pp. 699–717.

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Schleisenger, M.H., Wall, S.D., *et al.,* ''Part X. Gastrointestinal Diseases'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 656–807.

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[FR Doc. 01–29027 Filed 11–21–01; 8:45 am]

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Federal Register

Friday,
November 23, 2001

Part III

Department of the Interior

Bureau of Land Management

43 CFR Parts 3600, 3610, 3620 and 3800
Mineral Materials Disposal; Sales; Free Use; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3600, 3610, 3620, and 3800

[WO–320–1430–PB–24 1A]

RIN 1004–AD29

Mineral Materials Disposal; Sales; Free Use

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is amending its mineral materials regulations by adding or amending provisions on inspection of operations, production verification, contract renewal, procedures for cancellation, bonding, and appeals. The final rule also addresses the rights of purchasers and permittees versus subsequent users of the same land. BLM is amending the regulations in part because notices of intended sale of mineral materials have inspired speculative entries conflicting with the proposed sale, and because BLM has encountered difficulties in verifying production. These amendments are necessary to prevent entries and uses begun after a planned sale has been announced from interfering with the sale. The final rule also reorganizes and simplifies the regulations on mineral materials disposal, and makes a conforming amendment in BLM's regulations on Surface Management of mining claims.

EFFECTIVE DATE: December 24, 2001.

ADDRESSES: You may send inquiries or suggestions to Director (320), Bureau of Land Management, Room 501 LS, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Durga N. Rimal, Solid Minerals Group, at (202) 452–0350. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

I. Background

Under the mineral materials program, BLM manages the exploration, development, and disposal of materials such as sand, stone, gravel, and other common rocks. Our primary goal is to make Federal mineral materials available by sale or free use permit when it will not be detrimental to the public interest. BLM is also responsible for the planning and inventory of mineral materials on the public lands, and prevention and abatement of their unauthorized use. BLM monitors sites, and inspects and verifies production, to ensure compliance with the terms of the contract or permit. This final rule does not address vegetative materials, such as timber.

The general authority for the Mineral Materials Program is the Act of July 31, 1947, as amended (30 U.S.C. 601 *et seq.*), commonly referred to as the Materials Act. This Act authorizes the Secretary of the Interior to dispose of mineral and vegetative materials from public lands. This final rule revises the regulations on disposal of mineral materials, and makes two technical amendments and corrects cross-references in the subpart on free use of petrified wood.

The proposed rule was published on September 14, 2000 (65 FR 55864). BLM received 10 comments on the proposed rule. We received 3 comments from business interests, 1 from a private attorney, 1 from a State government agency, 4 from BLM field employees, and 1 from an individual without stated affiliation.

II. Discussion of Comments

Most of the comments were generally favorable to the proposed rule, and 4 of the public comments specifically stated that the proposed rule represented an improvement over the previous regulations. However, one of the generally favorable comments, endorsed by 2 others, stated that the question and answer format followed in the proposed rule was confusing.

Many studies have shown that comprehension of user manuals, regulations, and the like improves when they employ this question and answer format. Readers generally find them more user-friendly as well. Therefore, BLM will continue to use this format in most of its section headings. In a few instances, of course, single-word or short-phrase headings are more appropriate. This rule also use headline-type headings to mark major subject changes within subparts in the regulations. This should help you navigate the table of contents.

In the remainder of this portion of the preamble we will discuss those comments that suggested changes in specific provisions in the regulatory text, in order by section number.

Subpart 3601—Mineral Materials Disposal; General Provisions

Section 3601.5 Definitions

One comment stated that it should be made clear in the definition of ''public lands'' that ''any lands and interest in lands'' includes the mineral estate. The definition we used in the proposed rule is the standard definition, derived from the Federal Land Policy and Management Act of 1976 (FLPMA), which certainly intends to include the mineral estate. The public generally understands this.

The same comment continued by discussing the issue of split estate lands where the United States owns the mineral interests but the surface is private or under the jurisdiction of State or local government. The comment suggested that we should clarify and expand the language in the definition and the regulations at §§ 3601.1 and 3601.13. Because the reasons for estates being split in this way are many, and the statutory authorities are varied, we have included this discussion in the BLM Manual (see BLM Manual 3600) rather than in the regulations.

We asked in the preamble to the proposed rule for comments on the definition of ''public lands,'' noting that the Department of Agriculture uses a definition that excludes acquired lands in its administration of the Materials Act. We received no comments on this issue. We are continuing to review the definition of ''public lands'' under the Materials Act. As this review is still pending, we have retained for now the definition from the previous version of the rule. If we conclude that the definition should be changed, we will publish the proposed change in the **Federal Register**.

Section 3601.12 What Areas Does BLM Exclude From Disposal of Mineral Materials?

One comment raised the question whether language should be added to state that materials will not be disposed of from lands identified as prohibiting disposal in an approved land use plan. This is addressed in BLM's planning regulations (see 43 CFR 1610.5–3(a)), which require that ''All future resource management authorizations * * * conform to the approved plan.'' However, for the convenience of our customers, we have added a paragraph to this effect in this section.

Section 3601.13 How Can I Obtain Mineral Materials From Federal Lands That Have Been Withdrawn To Aid a Function of Another Federal Agency or of a State or Local Government Agency?

We realized from the comments on this section that the wording of both the question and answer was confusing. We have revised the wording of the question to track more closely the language of the statute, 30 U.S.C. 601. As required by the statute, this section gives veto power over mineral materials development to another Federal agency or State or local government for whose benefit the federal lands have been withdrawn. We have revised the answer to state simply the statutory requirement that if you wish to obtain mineral materials from such lands, the other agency must consent. This section does not address split estates, which, as stated above, are discussed in the BLM Manual rather than in the regulations.

One comment stated that BLM appeared to be abdicating its responsibility in making mineral materials available to the public. The statute, 30 U.S.C. 601, does not allow BLM to dispose of the mineral materials in this instance without the consent of the other agency. The same comment stated that the process called for in this section was cumbersome, especially in the context of competitive sales, because an applicant who has gone through the expensive process of obtaining a surface use permit from a surface management agency has no assurance of winning the competitive contract. There is no need to obtain a surface use permit before ascertaining whether the other agency will consent to the mineral materials disposal. If the agency does consent, and BLM initiates the disposal, an applicant can bid on the contract without first obtaining a surface use permit.

Section 3601.14 When Can BLM Dispose of Mineral Materials From Unpatented Mining Claims?

One comment, which was endorsed by two others, expressed strong support for this provision, saying that it will promote development of mineral resources while providing adequate safeguards for the mining claim owner, and would discourage speculation in questionable mining claims. The comment pointed out that purchasers of mineral materials would no longer face the cost of a mining claim contest.

Another comment stated that the wording of this provision was too tentative and conditional. The respondent suggested that BLM should require a waiver from the mining claimant before disposing of mineral materials from an unpatented claim. The comment also recommended removing the final sentence from proposed § 3601.14. This sentence provides that when a mining claimant refuses to sign a waiver, BLM will make sure that disposal would not be detrimental to the public interest, and will consult with the Solicitor's Office if necessary before proceeding with the disposal. We decided not to change the rule in response to this comment because the suggested changes do not address the situation where a mining claimant refuses to sign a waiver. We have retained the language in the proposed rule, which sets up an orderly process for BLM to follow to pursue the public interest.

This change also requires that we amend 43 CFR 3809.101(d), which addresses sale of mineral materials from unpatented mining claims, to conform with this final rule. Therefore, we are amending that paragraph to allow sales of mineral materials absent a waiver from the mining claimant following the procedures in this section, 3601.14. This will allow BLM to dispose of materials if it is not detrimental to the public interest and if we find that disposal would not impair the rights of the mining claimant.

One comment suggested the possibility of distinguishing between pre-1955 unpatented claims and later mining claims. We do not believe this distinction is necessary. Solicitor's Opinion No. M–36998, ''Disposal of Mineral Materials from Unpatented Mining Claims,'' June 9, 1999, concludes that BLM's authority to dispose of mineral materials from unpatented mining claims is based on the Materials Act of 1947, and that authority was left intact by the amendments of the Surface Resources Act of 1955, 30 U.S.C. 601 *et seq. Id.* at n.4 and accompanying text. BLM will proceed under the guidelines in § 3601.14 for all unpatented mining claims, consulting with the Solicitor's Office when necessary.

One comment asked whether BLM can establish a community pit on a mining claim. The regulations do not expressly prohibit the opening of a community pit over an unpatented mining claim. If such disposal were possible without endangering or materially interfering with prospecting, mining, or processing operations, or uses reasonably incident thereto, BLM would follow the procedures in § 3601.14 before deciding to proceed.

Section 3601.21 What Rights Does a Person Have Under a Materials Sales Contract or Use Permit?

One comment addressed this section, recommending that BLM separately authorize under a right-of-way associated uses such as a hot mix plant or a concrete batch plant. The comment pointed out that this would provide the public with additional revenue, and stated that the matter can be a subject for the BLM Manual or a handbook. The comment asked whether such uses as an asphalt mix table would be included in a contract or free use permit area, or in a separate right-of-way authorization.

In the aggregate business, mining, crushing, washing, screening, and separation of materials are processes integral to production of such value added items as asphalt concrete or ready-mix concrete. The regulations could separate the value-adding activities from the mining and extraction processes and require a separate authorization such as a right-of-way permit. However, ready-mix concrete or asphalt concrete batch plants are generally movable, not permanent features. Keeping all activities together and confined to a small area (generally already disturbed by mining) is desirable from an environmental point of view. We believe that contemplated use of concrete or asphalt mix plants should be included in the mining plan and considered in analysis under the National Environmental Policy Act during BLM's permitting process. No change is necessary in the final rule.

Section 3601.30 Pre-application Activities—How and When May I Sample and Test Mineral Materials?

Comments asked what happens if someone with a letter authorizing exploration under this section fails to submit sampling and testing findings. Another comment stated that the rule should allow BLM to approve exploration under sales contracts or free use permits as well as before their issuance.

Of course, it is possible that a person with an authorization to explore may choose not to explore. Aside from this, experience under the existing regulations, which contain a substantively identical provision, has not demonstrated a need for monetary penalties for failure to submit exploration findings. Furthermore, § 3601.60 allows BLM to cancel a contract or permit if the party fails to comply with any applicable regulation. This provides sufficient incentive for compliance with this requirement.

Sampling and testing are part of mineral material extraction that BLM authorizes under sales contracts or free use permits. Permittees or purchasers need no additional authorization within the permit or contract area.

Section 3601.41 What Information Must I Include In My Mining Plan?

One comment stated that the information listed under this section only begins to address what is needed in a mining or reclamation plan, and that operators should closely coordinate with BLM in preparation of both mining and reclamation plans. The comment suggested that it would be helpful if BLM were to provide a proposed mining plan outline, a copy of the BLM reclamation handbook, and other agency requirements. We agree that applicants should coordinate closely with BLM when preparing mining plans. The information the respondent suggested we provide is available in BLM Field Offices, and we can provide copies of sample plans and instructions if you need them.

Another comment suggested that we include ''depth'' of operations as one of the parameters that operators must include in a mining plan, and that we include ''the location of the soil/growth medium stockpile'' as an item in the reclamation plan. We have adopted the former suggestion in the final rule. However, we believe there is no need to pinpoint the location of the soil/growth medium stockpile, so long as the area it will disturb is indicated. That information is sufficiently covered in the description of information that you must include in the mining plan.

Section 3601.44 How and When May My Mining or Reclamation Plan Be Modified?

One comment suggested that the regulations elaborate on stop orders that BLM could issue under this section if a purchaser fails to modify a plan to BLM's satisfaction. The comment also asked that the regulations provide for penalties for such failure. The comment pointed to the regulations on use and occupancy of mining claims in 43 CFR subpart 3715 as a model. The regulations in subpart 3715 address abatement of unauthorized use and occupancy of unpatented mining claims. Unauthorized use and occupancy is a much more widespread and serious problem in the mining industry than failure to modify mining plans is in the mineral materials industry. We believe the consequences of failure to comply with these regulations—possible cancellation or suspension of the contract or permit—are serious enough without bringing to bear the heavy artillery of criminal penalties.

Another comment stated that this provision should direct BLM to provide justification before requiring a purchaser or permittee to modify an approved plan, and that the proposed rule would encourage BLM to act arbitrarily and abrogate terms of a binding contract. The rule limits BLM's discretion to require plan modification. We can do so only when we can point to changed conditions or an oversight that needs to be corrected. We believe that these limitations preclude arbitrary action. Each contract will state that it includes the requirements of all regulations, including this section, so operators are on notice that BLM can modify the plan if necessary. In the final rule we have added language providing for BLM to consult with the purchaser or permittee before requiring modifications.

Section 3601.51 How Will BLM Inspect My Operation?

One respondent, endorsed by two others, supported the inspection provisions in this section, stating that they codify how BLM field offices have been operating in his area. Another comment suggested that the regulations should also allow BLM to inspect weight tickets, truck logs, and other records of this type. We have added such a provision to the final rule in order to improve our ability to account for production.

Section 3601.61 When May BLM Cancel My Contract or Permit?

and

Section 3601.62 Cancellation Procedures.

One respondent, endorsed by two others, supported the cancellation provisions in these two sections, stating that the cancellation procedures give purchasers reasonable notice of BLM expectations. They agreed that a notice of intent to cancel with a period of time to rectify a problem or prove no wrongdoing is a common way of dealing with disputes in private mineral leases.

We have simplified the wording of § 3601.61(b), which in the proposed rule stated that BLM could cancel your contract or permit if you failed to comply with ''any applicable regulations, including the inspection requirements of § 3601.51.'' Because ''any applicable regulations'' necessarily includes the inspection requirements of § 3601.51, we determined that the reference to inspection requirements was superfluous, and we removed it.

Section 3601.71 What Constitutes Unauthorized Use?

One comment asked how the prohibition of extracting, severing, or removing mineral materials from public lands applies to split estate lands, where the surface owner may use mineral materials for purposes of improving the surface, so long as the owner does not remove the materials off-site. We have added a paragraph to this section stating BLM's long-standing policy that without a contract or permit, or other express authorization, a surface estate owner may make only minimal personal use of federally reserved mineral materials within the boundaries of the surface estate. Minimal use would include, for example, moving mineral materials to dig a personal swimming pool and using those excavated materials for grading or landscaping on the property. It would not include large-scale use of mineral materials, even within the boundaries of the surface estate.

Subpart 3602—Mineral Materials Sales Applications

Section 3602.12 How Does the Mineral Materials Sales Process Affect Other Users of the Same Public Lands?

Several comments addressed this section, supporting the language that provides that BLM's designation of a tract for a mineral materials sale establishes, for the ultimate purchaser, a superior right over subsequent third party entries or applications. These comments said that the provision gives the mineral producer certainty as to the status of its interest and protects its investment.

One comment asked for clarification as to exactly what period of time the superior right pertains. We have amended this section in the final rule to make it clear that the superior right pertains to the entire term of the sales contract or permit, including any renewal periods, of a contract or permit issued within the 2-year period following the date BLM notes the designation in the public land records. We have further amended his section to provide that the superior right applies to subsequent contracts or permits that BLM authorizes within 2 years after the previous contract or permit expires or terminates. This provision would prevent other claimants from speculatively establishing claims when BLM designates tracts in the hope that BLM contracts or permits will terminate before the mineral materials are exhausted. It allows BLM the same time period to enter into another contract or issue a permit for the remaining mineral materials and gives subsequent

purchasers or permittees the same certainty that the first purchaser or permittee enjoyed. This principle applies no matter how many successive contracts or permits there may be.

Section 3602.13 How Does BLM Measure and Establish the Price of Mineral Materials?

One comment, endorsed by two others, supported this provision, saying that it follows private industry standards, and that the reappraisal provisions also track industry practices, which allow for changes in unit price over time. This comment said that the two-year window when the price is fixed is reasonable.

One comment suggested that we amend paragraph (c), which allows the purchaser or permittee to choose between the two measurement methods: In-place volume or weight equivalent, to provide that BLM may designate the method of measurement that operators must use. We agree, and have amended the rule to allow BLM to choose the method. BLM will not always exercise this option, but will allow the operator to make the choice in many cases.

Section 3602.14 What Kind of Financial Security Does BLM Require?

Several comments addressed this section. One comment stated that the bonding provision is cumbersome because it appears to set up a dual bond requirement—a performance bond of 5 percent, and a reclamation bond of at least $500. The intent of the proposed rule was not to require two bonds, but to set up a two-stage calculation to determine the required amount of the bond, which BLM could have used to enforce any part of the contract performance.

BLM has determined that the two-stage calculation is unnecessary, and we have removed the requirement that the bond include 5 percent of the total contract price. A performance bond large enough to cover reclamation costs should be sufficient for environmental protection, and BLM can still use the bond amount to enforce any part of the contract performance. For average operations (contracts of $57,000) the bond amount under these new requirements is expected to decrease from $11,400 to $5,000, a reduction of $6,400. While on its face, this reduction might appear to afford less protection to the Federal Government, it actually only recognizes that the relatively high bonding requirements of the mineral materials program have been unnecessary. Moreover, we will also be holding the purchaser's cash deposit of 5 percent of the contract value, or $500, whichever is larger, which will further guarantee performance. These changes make the bonding system for mineral materials more consistent with bonding standards in other minerals programs, such as oil and gas, leaseable minerals, and the mining law. Further, if the purchaser removes excess materials, we can use trespass procedures under 43 CFR 9239.0–7 and 9239.0–8 to recover damages.

One comment recommended that BLM accept other forms of security besides performance bonds, and went on to suggest examples of types of security that other agencies accept. The comment suggested that we add language allowing ''any other form of financial security which is acceptable to the Secretary.'' We have adopted the suggestion that we accept other forms of security, and have added irrevocable letters of credit to the forms that BLM will accept. We have also made clear that surety bonds can be arranged or paid for by third parties. We have not adopted the broad language suggested by the comment because we have determined that the rules should not provide open-ended discretion in the bonding area.

One comment urged that BLM not set a maximum bond of 20 percent of contract value for contract sales less than $2,000. The respondent raised two concerns: First, reclamation costs may exceed the bond in some circumstances, and second, the Federal upper limit may cause problems with State and local bonding requirements. BLM does not view these concerns as outweighing the reasons for the provision.

- This bonding provision is necessary to protect the interests of small purchasers. Many of our small sales are from community pits and common use areas, where bonds are generally not needed at all. For other small sales, BLM takes extra care to select sites with minimal possibility of environmental damage and therefore low reclamation costs.
- BLM bonding levels should have no effect on State or other agency bonding policies and requirements. It is quite common for different levels of government to have different bonding requirements.

Finally, one comment pointed out that paragraph (a)(2) of this section as proposed would seem to require bonding for sales of $2,000 or more from community pits, and said that this seems to be an unnecessary burden on business. BLM agrees, and, as stated above, in the final rule, we have removed the provision requiring a 5 percent bond.

Section 3602.21 What Payment Terms Apply to My Mineral Materials Sales Contract?

Several comments addressed this section. Three comments, one of them endorsed by two others, stated general support for this section, pointing out that the procedure outlined in this section tracks the standard operating procedure in private sales.

One comment suggested removing the requirement for payment in lieu of production in § 3602.21(a)(3). The respondent thought the requirement in paragraph (a)(2)(iii) that the full contract amount be paid before contract expiration should sufficiently assure BLM that the purchaser will make full payment. BLM has not adopted this comment in the final rule. The provision for in lieu payments promotes diligent development and deters speculative holding of mineral deposits. Without it, purchasers may be tempted to obtain large contracts for speculative purposes or to reduce competition.

One comment suggested that the regulation should allow an annual payment at the end of the year for mineral materials actually mined during the year. We have amended this section in the final rule to allow annual payments for the upcoming year based on the amount produced in the previous year or an estimate of production for the upcoming year. If you choose to make payments this way, you must reconcile the amount as the year progresses.

The proposed rule provided, at § 3602.21(a)(2)(iii)(A), that you must make installment payments monthly in an amount equal to the value of the mineral materials you removed that month. We have revised this section to specify that the payment must be made by the 15th day following the end of the month for which you are reporting, to give you time to determine the value of the materials removed.

Section 3602.22 When Will a Contract Terminate?

Two comments addressed this section, stating that a contract should terminate when the purchaser has removed the contracted-for amount of mineral materials rather than when its term expires. Automatically terminating a contract when the amount of material contracted for has been removed would conflict with contract renewal provisions and could conflict with the purchaser's obligation to perform reclamation. However, we have added a provision that the contract or permit will terminate when the operator has completed both production and all required reclamation. Once an operator

completes all reclamation, there is no longer any reason to encumber the land with a contract or permit, as the operator has no interest in renewal, and BLM's interest in reclamation is satisfied.

Section 3602.23 When Will BLM Make Refunds or Allow Credits?

The proposed rule provided that BLM would reduce the amount of any refund by the amount of the administrative cost of processing the disposal action. In the final rule, we have amended this language to provide that BLM will reduce the refund or credit due to administrative costs only when the refund or credit results from terminating the contract by mutual agreement. Our intention was not to withhold administrative costs when purchasers have simply overpaid or when our initial estimate of mineral materials available was mistaken.

Section 3602.24 When May I Assign My Materials Sales Contract?

One comment stated that paragraph (b)(1) of this section seems not to require an assignee to provide a reclamation bond. This comment is related to the comment on § 3602.14, and is based on the notion that that section required dual bonds. Our revision of § 3602.14 to require a performance bond based only on estimated reclamation costs eliminates this confusion. Nevertheless, we have also amended this provision to require the assignee to provide a ''financial guarantee'' under § 3602.14, rather than a ''performance bond.''

Section 3602.26 If I Assign My Contract, When Do My Obligations Under the Contract End?

Two comments addressed this section. One respondent thought that the word ''accrual'' did not pertain to obligations and liabilities, but only to gains or additions, and suggested that the provision is unnecessary, because operators can negotiate responsibility for reclamation and similar matters at the time of assignment. The other comment suggested that this section conflicted with § 3602.15, which provides for cancellation of the assignor's bond obligations when the assignee provides an appropriate bond. We have amended this provision in the final rule by removing the phrase ''such as reclamation.'' This phrase produced more confusion than clarification in the proposed rule. We believe that the term ''accrual'' is appropriate for obligations as well as benefits, and the assignor is responsible for all contract obligations that accrued before BLM approves the assignment, regardless of whether the assignor's bond obligations have been canceled.

Section 3602.28 What Records Must I Maintain and How Long Must I Keep Them?

and

Section 3602.29 How Will BLM Verify My Production?

The several comments addressing these sections all supported the production verification methods in the proposed rule. One comment recommended that BLM require monthly reporting. We have not adopted this comment in the final rule, but have revised this provision to say that you must submit at least one report per contract year. Both the proposed and final rules make it clear that BLM may require reporting more frequently than annually.

Another comment recommended that we require volumetric surveys only in certain circumstances such as large volume commercial sales, saying that the cost of these surveys does not justify the public benefit. We agree, and this is how BLM will implement this section. It is not necessary to provide this degree of detail in the regulations, because BLM Manuals and handbooks will provide this instruction to production verification personnel.

Section 3602.31 What Volume Limitations Generally Apply to Noncompetitive Mineral Materials Sales?

and

Section 3602.32 What Volume and Other Limitations Pertain to Noncompetitive Sales Associated With Public Works Projects?

Five comments supported the increased volume limitations in these sections of the proposed rule. One of them suggested further increases, or even eliminating the limits, on noncompetitive sales. In the final rule, BLM has raised the limit on the total aggregate amount of noncompetitive sales made in any one State for the benefit of any one purchaser, in any period of 12 consecutive months, to 300,000 cubic yards (or weight equivalent). We are not changing the provision for maximum volume limitation for individual noncompetitive sales. We will monitor the mineral materials program and consider raising the volume limit for noncompetitive sales in the future, if we find a need for that change.

Section 3602.34 What Is the Term of a Noncompetitive Contract?

One comment recommended that non-competitive mineral materials purchasers be offered the same renewal options and terms as competitive purchasers. The comment cited a specific case, where a mineral trespass situation resulted in a settlement agreement containing a provision under which BLM allowed the offending company multiple sequential noncompetitive contracts during a 10-year period so that we could recover lost revenues from the trespass property. The comment went on to say that the local BLM office should allow other similar noncompetitive sales contracts until that settlement agreement terminates. BLM has not adopted this comment in the final rule. The instance described in the comment involved unique circumstances. The governing statute directs the Secretary to dispose of mineral materials by competitive bidding unless it is impracticable to obtain competition. 30 U.S.C. 602. Because the statute favors competitive contracts, the regulations do not provide for noncompetitive contracts to include the same terms as competitive contracts.

Section 3602.45 What Final Steps Will BLM Take Before Issuing Me a Contract?

In the proposed rule, this section was entitled, ''What conditions must I meet before BLM will issue me a conract?'' Although no comments addressed this section, on review we have decided that the section heading was not completely descriptive. We have given the section a new heading, partially reorganized the section, and added paragraph headings to make its organization clearer. We have also revised paragraph (g) to explain that additional provisions and stipulations that BLM adds to the contract will be for the purpose of conforming to the provisions of the competitive sale notice and to address environmental or other site-specific issues. The standard contract form approved by the Office of Management and Budget is a basic form that can be used for any kind of sale. It is not all-inclusive and states that the contract will include the stipulations and the mining plan attached to it. Provisions that relate to mining on a specific tract of land must be added to the contract. We have not made substantive changes in this section.

Section 3602.47 When and How May I Renew My Competitive Contract?

One comment, endorsed by two others, supported this provision as promoting mineral development

because it protects the initial purchaser. It pointed out that the life span of a mineral deposit can be decades, and said that the previous regulations provided no incentive for exploration and development because there was no guarantee that the purchaser would be in place for more than one contract term.

Another comment recommended amending the section to allow renewals of noncompetitive contracts, saying that the noncompetitive purchaser has the same investment in the application process, site and access preparation, and, with some commodities, market development costs, as the competitive purchaser. BLM is not amending the final rule in response to this comment. First, most noncompetitive contracts are for minerals in community pits and common use areas, where site and access preparation are not economic factors. Second, the regulations provide for a one-year extension (see § 3602.27) if the purchaser was unable to finish operations under the contract for reasons beyond his or her control and meets the appropriate procedural deadline described in § 3602.27. Finally, as discussed above, the governing statute requires competitive contracts whenever competition is practicable, so BLM will not allow unlimited renewals when we did not award the initial contract on a competitive basis.

One comment asked for assurance that renewals of competitive contracts would be done non-competitively. We amended this section to make it clear that once you have been awarded a contract through competitive bidding, you may apply for a renewal of that contract without further competitive bidding. BLM's experience with the mineral materials markets has shown that we need to offer competitive contracts with options for renewal to attract the competition that will bring the greatest economic benefit for the United States. In essence, we are offering for competitive bidding both a stated amount of mineral materials and options for additional amounts, in a process of two or more stages. Adding options for contract renewal at the time of competitive bidding allows BLM to improve the economic return to the United States.

One comment stated that this section in the proposed rule, with its deadline for requesting a renewal 90 days before contract expiration, conflicted with section 3602.21(a)(2)(iii), which directs purchasers to pay the full amount of their contracts no later than 60 days before the contracts are to expire. There is no conflict between these two provisions. A purchaser who wants to renew a competitive contract must pay the full contract value before applying for renewal at least 90 days before the contract expires. Others, for whom renewal is not of interest, must pay the full contract value no later than 60 days before contract expiration. Those who wish to renew simply have an earlier payment deadline.

Section 3602.48 What May BLM Require When Renewing My Contract?

One comment, endorsed by two others, supported the reappraisal requirements in this section. The respondent said that his contracts commonly provide for a change in unit price over time.

Section 3602.49 When Will BLM Issue a Non-Renewable Contract?

We received no comments on this section. We decided, however, to amend paragraph (c) to provide that if fewer than 120 days remain on your contract after the effective date of this rule, BLM may approve your renewal request submitted less than 90 days before the contract expires if we decide the contract qualifies for renewal and we have sufficient time to process your request before your contract is due to expire. We added this provision to give an opportunity for contract renewal to purchasers who have existing contracts on the effective date of this rule, but who would be unable to meet the 90-day deadline due to the short time remaining on the contracts after the effective date. (Since this paragraph is of strictly limited applicability, we will remove it from the regulations at the earliest opportunity in an administrative final rule.)

Section 3603.14 What Plans Do I Need to Prepare To Mine or Remove Mineral Materials From a Community Pit or Common Use Area?

This section in the proposed rule provided that BLM would not require a mining or reclamation plan before authorizing mining or removing mineral materials from a community pit or common use area. One comment urged that BLM amend this section to give us discretion as to whether to require a mining plan in these instances. We have changed the final rule to state that BLM generally will not require a mining or reclamation plan in such cases, but may require a plan if we find that circumstances warrant it. Not all removals are of such a scale that we need a mining plan.

Section 3603.22 What Fees Must I Pay to Cover the Cost of Reclamation of Community Pits and Common Use Areas?

One comment noted that the rule contained no bonding provision to cover reclamation of community pits. Although it was not clear, the comment appeared to say that the rule should provide for bonding of operations in community pits if the operator elects to perform reclamation in lieu of paying a reclamation fee. We have amended the rule in response to this comment, giving BLM discretion to require a bond in these circumstances, in either community pits or common use areas. However, our normal practice is to collect a reclamation fee and not require a bond. The reclamation fee is paid under Section 305 of FLPMA (43 U.S.C. 1735) into the Fund for Repair of Damaged Lands. BLM uses moneys from this fund to pay for reclamation of exhausted community pits.

Section 3604.11 How Do I Apply for a Free Use Permit?

One comment suggested that this section require or allow a letter from the applicant to BLM in place of BLM Form 5510–1. It said that applicants often incorrectly fill it out and must resubmit it. The comment said that personal experience with letter transactions has been favorable. We have amended this provision in the final rule to allow letter applications for free use permits. You may send a letter or use BLM Form 5510–1.

Section 3604.22 What Conditions and Restrictions Pertain to My Free Use Permit?

One comment asked what recourse BLM has if a free use permittee violates a permit restriction or condition, and suggested that it may be politically difficult to hold a local government in trespass. We have made no change in the final rule in this respect. We have the authority and responsibility to initiate trespass proceedings in any case where they are indicated. Of course, we would carry out such proceedings only as a last resort when persuasion fails.

III. The Final Rule

The final rule substantially reorganizes parts 3600, 3610, and 3620. We are reorganizing the regulations for two reasons: (1) To make them read more logically and clearly; and (2) to conform more closely to Office of the Federal Register numbering conventions. The following table shows how numbers are changed from the previous regulations to the final rule.

Section Conversion Table

Old section	New section
Group 3600 heading	none
Group 3600 Note	§ 3601.9
Part 3600	Part 3600
Subpart 3600	Subpart 3601
§ 3600.0–1	§ 3601.1
§ 3600.0–3	§ 3601.3
§ 3600.0–3(a)(3)	§ 3601.12
§ 3600.0–4	§ 3601.6
§ 3600.0–5	§ 3601.5
§ 3600.0–8	§ 3601.8
Subpart 3601	none
§ 3601.1	§ 3601.10
§ 3601.1–1(a)(1)	§ 3601.14
§ 3601.1–1(a)(2)	§ 3601.12
§ 3601.1–2(a), (c)	§ 3601.21
§ 3601.1–2(b)	§ 3601.22
§ 3600.0–3(a)(2)	§ 3601.13
§ 3601.1–3	§ 3601.11
Subpart 3602	none
§ 3602.1	§ 3601.40
§ 3602.1–1	§ 3601.41
§ 3602.1–2	§ 3601.42
§ 3602.1–3(a), (b)	§ 3601.43
§ 3602.1–3(c), (d)	§ 3601.44
§ 3602.2	§ 3601.30
§ 3602.3	§ 3601.52
none	§ 3601.51
none	§ 3601.60
none	§ 3601.61
none	§ 3601.62
Subpart 3603	none
§ 3603.1	§§ 3601.70 through 3601.72
none	§ 3601.80
Subpart 3604	Subpart 3603
§ 3604.1(a)	§ 3603.10
§ 3604.1(b)	§ 3603.11
§ 3604.1(c)	§ 3603.12
§ 3604.1(d) (first sentence).	§ 3603.13
§ 3604.1(d) (second sentence).	§ 3603.14
§ 3604.2	§ 3603.20
§ 3604.2(a)	§§ 3603.21 and 3603.22(b)
§ 3604.2(b)	§ 3603.22(a)
Part 3610	none
Subpart 3610	Subpart 3602
§ 3610.1	§ 3602.10
§ 3610.1–1	§ 3602.11
none	§ 3602.12
§ 3610.1–2	§ 3602.13
§ 3610.1–3(a)(1)–(5)	§ 3602.21(a)
§ 3610.1–3(a)(6)	§§ 3602.21(b), 3602.22(a)
§ 3610.1–3(b)	§ 3602.22(b)
§ 3610.1–4	§ 3602.23
§ 3610.1–5	§ 3602.14
none	§ 3602.15
§ 3610.1–6(a), (b)	§ 3602.24
§ 3610.1–6(c)	§§ 3602.25, 3602.26
§ 3610.1–7	§ 3602.27
none	§ 3602.28
§ 3610.1–3(a)(7)	§ 3602.29
§ 3610.2	§ 3602.30
§ 3610.2–1	§ 3602.31
§ 3610.2–2	§ 3602.32
§ 3610.2–3	§ 3602.33
§ 3610.2–4	§ 3602.34
§ 3610.3	§ 3602.40
§ 3610.3–1(a)	§ 3602.41
§ 3610.3–1(b)	§ 3602.42(c)
§ 3610.3–2	§ 3602.42(a), (b)
§ 3610.3–3	§ 3602.43
§ 3610.3–4	§ 3602.44
§ 3610.3–5	§ 3602.45
§ 3610.3–6	§ 3602.46
none	§ 3602.47
none	§ 3602.48
none	§ 3602.49
Part 3620	none
Subpart 3621	Subpart 3604
§ 3621.1	§ 3604.10
§ 3621.1–1	§ 3604.11
§ 3621.1–2	§ 3604.21
§ 3621.1–3	§ 3604.23
§ 3621.1–4(a), (c)–(d)	§ 3604.22
§ 3621.1–4(b)	§ 3604.13
§ 3621.1–5	§ 3604.24
§ 3621.1–6	§ 3604.25
§ 3621.1–7	§ 3604.26
§ 3621.2(a)	§ 3604.12(a)
§ 3621.2(b)	§ 3604.12(b)
§ 3621.2(c)	§ 3604.27
Subpart 3622	Subpart 3622

A. How Does BLM Dispose of Mineral Materials? (See § 3601.6.)

BLM disposes of mineral materials from public lands by selling them and, under some circumstances, giving them away. We dispose of materials from exclusive sites used by one operator or nonexclusive sites (community pits or common use areas) used by more than one operator. Under the final rule and BLM policies, disposal methods are as follows:

1. Negotiated Sales (*see* § 3602.30 *et seq.*).

BLM will negotiate a sale contract for quantities of materials not greater than 200,000 cubic yards, with certain exceptions detailed in the regulations. The price will be fair market value of the minerals as BLM determines through an appraisal. Contracts have a maximum term of 5 years, with a possible one-time extension not greater than one year.

2. Competitive Sales (*see* § 3602.40 *et seq.*).

For quantities of materials greater than 200,000 cubic yards, or if BLM is aware that there is competitive interest in the materials site, we advertise the availability of the material at the particular site and sell it to the highest bidder. Contracts issued through this process have a term of no more than 10 years, but BLM may allow a one-time extension of up to one year and you may apply for renewal of the contract to purchase additional material at the site.

3. Free Use Permits (*see* subpart 3604).

BLM issues free use permits for sand and gravel and other materials to government agencies and to non-profit organizations. A large part of mineral materials produced under the program is under free use permits to local, State, and other Federal Government agencies, including State and county highway departments, cities, and municipalities. As a government agency, you may obtain free use permits to extract specified quantities of material for public works projects. BLM may specify the amount you may extract under a government agency free use permit, and may allow your operation to continue for up to 10 years. You may not barter or sell the material.

BLM also issues free use permits to non-profit organizations for up to 5,000 cubic yards for any 12 consecutive months. These permits have a one-year term. If there is an additional need, you must apply for a new permit. You also may not barter or sell this material.

B. Surface Management Operations

BLM is responsible for monitoring the sites, inspection, and production verification to ensure compliance with the terms of the contract or permit. BLM seeks (1) accurate accounting for materials you remove, (2) proper compensation to the Federal Government, and (3) protection of the environment, public health, and safety. We may use field inspections and site surveys, or high-tech methods, such as aerial surveys or computer modeling, that quantify the volume of material removed. We generally base the frequency of inspections and the choice of verification method on the size and type of disposal.

Substantive changes in the final rule from the previous regulations include the following:

(1) The rule provides that BLM may dispose of mineral materials from unpatented mining claims in accordance with Solicitor's Opinion No. M–36998, Disposal of Mineral Materials from Unpatented Mining Claims, June 9, 1999. See § 3601.14.

(2) The rule requires permittees and purchasers to allow BLM to inspect their operations, conduct surveys, and estimate the volume and type of production. See § 3601.51.

(3) The rule adds a provision that when BLM designates a tract for sale of mineral materials, subsequent contracts or permits on that tract have priority over any subsequent conflicting mining claim, entry, or other use of the land. See § 3602.12.

(4) The rule allows BLM to cancel permits or sales contracts for failure of the purchaser or permittee to comply with the law, regulations, or contract or permit terms. It requires BLM to provide written notice of our intent to cancel,

allowing time to correct performance problems, to request an extension, or to show why the contract or permit should not be canceled. See §§ 3601.61 and 3601.62.

(5) The rule includes a cross reference to the Department of the Interior appeals regulations in 43 CFR part 4. See § 3601.80.

(6) The rule makes the provisions for reappraisal clearer. BLM will not reappraise sooner than 2 years after we issue the contract or complete a previous reappraisal. See §§ 3602.13 and 3602.48.

(7) The final rule amends the bonding requirements for mineral material sales by accepting qualified certificates of deposit and irrevocable letters of credit as surety bonds, and by changing bonding requirements for sales of $2,000 or more. We set bonds at more realistic levels, and they should ensure that amounts needed to cover the cost of reclamation will be available. See § 3602.14.

(8) The rule reduces the percentage amount BLM requires, under a material sales contract, for the first installment payment and in lieu of production payments. See § 3602.21.

(9) The rule provides that you must—

- Make monthly installment payments in an amount equal to the value of the materials removed the previous month, or
- Make an annual prepayment based on the previous year's production or a projection of the current year's production. See § 3602.21(a)(2).

(10) The rule allows purchasers with contract terms of 90 days or less to request contract extensions no later than 15 days instead of 30 days before the end of the contract. See § 3602.27.

(11) The rule strengthens and clarifies provisions allowing BLM to require purchasers of mineral materials to keep records to verify production and to make them available to BLM. BLM uses these records to ascertain whether purchasers have complied with regulations and contract terms. To allow BLM to verify production, the rule requires purchasers to submit production reports at least annually. It allows BLM to require purchasers to conduct volumetric surveys of the operation site as well. See § § 3602.28 and 3602.29.

(12) The rule increases the volume limitation for noncompetitive sales from 100,000 to 200,000 cubic yards. It also increases the limit for sales in any one State for the benefit of any one purchaser in a 12-month period from 200,000 to 300,000 cubic yards. The rule also increases the volume limitation for noncompetitive sales in support of a public works improvement program from 200,000 to 400,000 cubic yards. See § § 3602.31 and 3602.32.

(13) The rule allows the successful bidder in a competitive sale 60 days instead of 30 days to ratify and execute the contract. See § 3602.45.

(14) The rule adds a provision for renewing contracts, allowing a purchaser who has paid the full contract price for the purchased mineral material to apply for renewal of the contract to allow purchase of additional material from the same site. The maximum renewal term is 10 years, but there is no limit on the number of renewals BLM allows. However, each renewal requires a reappraisal, a new environmental analysis when we find it necessary, and a possible increase or decrease in the bond the purchaser must post. See § 3602.47.

These regulations apply from the effective date of the final rule to all future contracts and permits. They also apply to existing contracts and permits to the extent—

- The contract or permit incorporates future regulations, and
- The regulations are not inconsistent with the express terms of the contract or permit.

IV. Procedural Matters

The principal author of this final rule is Dr. Durga N. Rimal of the Solid Minerals Group, assisted by Ted Hudson of the Regulatory Affairs Group, Washington Office, Bureau of Land Management.

Regulatory Planning and Review (E.O. 12866)

This document is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an annual economic effect of $100 million or adversely affect in a material way the economy, an economic sector, productivity, competition, jobs, the environment, public health or safety, or other units of government or communities. A cost-benefit and economic analysis is not required.

During fiscal years 1996 through 1998, BLM annually issued an average of a little over 2,900 mineral materials free use permits and sales contracts, valued at a little less than $12 million over the life of the contracts. Of this value, about $4.2 million was disposed of under free-use permits, and about $1.3 million was sold in non-exclusive sales from community pits, with an average sale of about $570. There were 395 exclusive sales in an average fiscal year during the period, valued at a little less than $6.5 million, with an average sale of a little over $16,400.

During the next two fiscal years, this approximate sale and permit disposal rate continued. In fiscal year 1999, BLM processed 2,887 sales contracts and free-use permits for 12.8 million cubic yards of mineral materials, valued at $9.4 million. Of these, 2,344 were non-exclusive sales, totaling nearly 1.28 million cubic yards, valued at $1.57 million. Of the remainder, 332 were exclusive sales, totaling nearly 4.58 million cubic yards, valued at $4.3 million, and 211 were free-use permits, totaling 6.95 million cubic yards, valued at $3.54 million. There was production on 3,307 contracts and permits, some of which carried over from previous years, amounting to 10.9 million cubic yards, valued at $8.9 million.

In fiscal year 2000, BLM processed 3,542 sales contracts and free-use permits for 18.7 million cubic yards of mineral materials, valued at $15 million. Of these, 2,755 were non-exclusive sales, totaling nearly 1.36 million cubic yards, valued at nearly $1.4 million. Of the remainder, 500 were exclusive sales, totaling 6.6 million cubic yards, valued at nearly $5.7 million, and 287 were free-use permits, totaling 10.7 million cubic yards, valued at nearly $8 million. There was production on 4,801 contracts and permits, some of which carried over from previous years, amounting to 11.95 million cubic yards, valued at $9.8 million.

Average annual production for these 5 years, under existing and new permits and contracts (some being multi-year contracts), exclusive and non-exclusive, amounted to just under $9 million.

The changes proposed in this rule are:

1. Adding procedures for inspection, production verification, and cancellation of contracts;

2. Protecting material sales from interference by subsequent land users and claimants;

3. Allowing BLM to dispose of mineral materials from unpatented mining claims;

4. Reducing the amount of required installment payments;

5. Increasing the value threshold triggering the requirement for competitive bidding;

6. Allowing additional time to prepare and submit mining and reclamation plans;

7. Adding certificates of deposit and irrevocable letters of credit as acceptable financial instruments for bonds;

8. Ensuring that bonding amounts for sales contracts of $2,000 or more are adequate to perform reclamation; and

9. Adding provision for the renewal of competitive sales contracts.

These changes should not have appreciable effects on the economy, and any effects certainly will not approach $100 million annually.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The proposed rule will have no effect on disposal of mineral materials from national forest lands. The rule will not be in conflict with State regulations or requirements. The rule will have no effect on lands over which States have jurisdiction, other than to require a State's consent before materials may be disposed of from public lands that are withdrawn for its use, as already required. The rule expressly does not apply to national park lands or to Indian lands.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. BLM sells mineral materials at not less than the fair market value of the materials extracted, except in the instance of free use. The proposed rule will not have an effect on user fees.

(4) This rule does not raise novel legal or policy issues.

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). For the purpose of this section a ''small entity'', as defined by the Small Business Administration for mining and quarrying of nonmetallic minerals, except fuels, is considered to be an individual, limited partnership, or small company (together with its affiliates), with fewer than 500 employees. Most sand and gravel companies and other mineral material enterprises that purchase mineral materials from BLM are small businesses, employing fewer than 500 persons, and many governmental units that may obtain free use permits are also small entities.

Nationwide average production of crushed stone and sand and gravel used for construction for 1996–1998 was about $12.3 billion per year. The value of production from public lands is a small portion of this figure. For instance, the value of mineral materials produced from mineral material sales contracts averaged about $74 million or less than 2/3 of 1 percent of the national production. (Note that this represents the value of the product free on board (FOB) at the pit, not the fair market value of the in-place (in situ) material. Experience shows the average in-place value to be about 8% of the FOB price.) Even when we add production from free use permits the total annual production averages about $119 million, still under 1% of the national total. The specific changes in this rule, including changes in bonding requirements for material sales contracts of $2,000 or more, should not have an appreciable effect on small business. For average operations (contracts of $57,000) the bond amount is expected to decrease from $11,400 to $5,000, a reduction of $6,400. Therefore, the impact of this rule on the entire industry, including small business entities, is expected to be minor, and neither an initial Regulatory Flexibility Analysis nor a Small Entity Compliance Guide is required.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Will not have an annual effect on the economy of $100 million or more. See the discussion in the previous section of this preamble.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The rule should have little or no effect on prices of mineral materials, which are determined under the regulations by fair market value. The changes in the rule, which are described in the previous section of the preamble, should have no appreciable effect on costs.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. The rule should have marginal economic effects on a small segment of one industry. The mineral materials industry deals with materials that generally have high bulk and low unit value, and thus does not have appreciable foreign competition due to the high costs of transportation.

The Small Business Administration established the Small Business and Agricultural Regulatory Enforcement Ombudsman and ten Regional Fairness Boards to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman annually evaluates these enforcement activities and rates each agency's responsiveness to small business. If you wish to comment on enforcement aspects of this rule, you may call 1–888–734–4247.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. The previous regulations and these final regulations both allow State and local government agencies free use of mineral materials for public projects. Such governments must show that their proposed use is a public project, and meet certain other requirements stated in the regulations. The rule would not require anything of State or local governments other than an application for a free use permit. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings (E.O. 12630)

In accordance with Executive Order 12630, BLM has found that the rule does not have significant takings implications. No takings of personal or real property will occur as a result of this rule. Although the rule does include new provisions for contract cancellation, a contract issued under these regulations does not convey a property interest protected by the Takings Clause. A takings implication assessment is not required.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, BLM finds that the rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. The main connection the mineral materials program regulations have with other levels of government is in the context of free use of these resources. The rule does not place any new burdens on this use. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The rule does not preempt State law.

Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988, BLM finds that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. BLM consulted with the Department of the Interior's Office of the Solicitor throughout the drafting process.

Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

In accordance with E.O. 13175, we have found that this final rule does not include policies that have tribal implications. The Materials Act and these regulations expressly exclude Indian lands and lands set aside or held for the benefit or use of Indians from any effects of the statute or regulations (see § 3601.12). The regulations do not bar Indians or Tribes from buying mineral materials from public lands, although the abundance of these materials on Indian lands has made such purchases unnecessary. We do not know of any instances of tribal use of mineral materials from public lands.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

This rule is not a significant energy action. It will not have an adverse effect on energy supplies. The rule applies only to mineral materials like sand and gravel used in construction, not to energy minerals. To the extent that the rule relieves constraints on purchase and mining of construction materials that may be used in aid of developing energy minerals, it will have a marginally beneficial effect on energy supplies.

Paperwork Reduction Act

The regulations in part 3600 require information collections from 10 or more parties and submissions under the Paperwork Reduction Act. These information collection requirements have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1004–0103. BLM is collecting the information to allow us to determine if you are qualified to purchase or have free use of mineral materials on the public lands. You must respond to obtain a benefit.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C) is not required.

BLM has determined that any environmental effects that this final rule may have are too broad, speculative, or conjectural to lend themselves to meaningful analysis. Each sale of mineral materials other than from a community pit or common use area, each designation of the community pit or common use area itself, and each free use permit, will be subject to evaluation under NEPA. The final rule also provides that BLM will perform additional NEPA analyses as required before renewing mineral materials sales contracts. Therefore, the final rule is categorically excluded from environmental review under section 102(2)(C) of the National Environmental Policy Act, pursuant to 516 Departmental Manual (DM) 2.3A and 516 DM 2, Appendix I, Item 1.10, and does not meet any of the 10 criteria for exceptions to categorical exclusion listed in 516 DM 2, Appendix 2. Pursuant to Council on Environmental Quality regulations (40 CFR 1508.4) and the environmental policies and procedures of the Department of the Interior, the term ''categorical exclusion'' means a category of actions that do not individually or cumulatively have a significant effect on the human environment and that have been found to have no such effect in procedures adopted by a Federal agency and for which neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

43 CFR Part 3600

Governmental contracts, Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds

43 CFR Part 3610

Governmental contracts, Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds

43 CFR Part 3620

Public lands-mineral resources, Reporting and recordkeeping requirements.

Dated: October 15, 2001.

J. Steven Griles,

Deputy Secretary of the Interior.

Under the authorities cited below, and for the reasons stated in the Supplementary Information, BLM amends Subchapter C, Chapter II, Subtitle B of Title 43 of the Code of Federal Regulations, as follows:

1. Part 3600 is revised to read as follows:

PART 3600—MINERAL MATERIALS DISPOSAL

Subpart 3601—Mineral Materials Disposal; General Provisions

Sec.

Authority: 30 U.S.C. 601 *et seq.*; 43 U.S.C. 1201, 1732, 1733, 1740; Sec. 2, Act of September 28, 1962 (Pub. L. 87–713, 76 Stat. 652).

Subpart 3601—3601–Mineral Materials Disposal; General Provisions

Fundamental Provisions

§ 3601.1 Purpose.

The regulations in this part establish procedures for the exploration, development, and disposal of mineral material resources on the public lands, and for the protection of the resources and the environment. The regulations apply to permits for free use and contracts for sale of mineral materials.

§ 3601.3 Authority.

(a) BLM's authority to dispose of sand, gravel, and other mineral and vegetative materials that are not subject to mineral leasing or location under the mining laws is the Act of July 31, 1947, as amended (30 U.S.C. 601 *et seq.*), commonly referred to as the Materials Act. This authority applies to sale and free use of these materials. BLM's authority to allow removal of limited quantities of petrified wood from public lands without charge is section 2 of the Act of September 28, 1962 (Pub. L. 87–713, 76 Stat. 652).

(b) Section 302 of the Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1732) provides the general authority for BLM to manage the use, occupancy, and development of the public lands under the principles of multiple use and sustained yield in accordance with the land use plans that BLM develops under FLPMA.

(c) Section 304 of FLPMA (43 U.S.C. 1734) and the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701) authorize the U.S. Government to collect fees and to require reimbursement of its costs.

§ 3601.5 Definitions.

As used in this part the term:

Act means the Materials Act of July 31, 1947, as amended (30 U.S.C. 601, *et seq.*).

BLM means the Bureau of Land Management.

Common use area means a generally broad geographic area from which BLM can make disposals of mineral materials to many persons, with only negligible surface disturbance. The use is dispersed throughout the area.

Community pit means a relatively small, defined area from which BLM can make disposals of mineral materials to many persons. The surface disturbance is usually extensive in the confined area.

Mineral materials means, but is not limited to, petrified wood and common varieties of sand, stone, gravel, pumice, pumicite, cinders, and clay.

Performance bond means a bond to ensure compliance with the terms of the contract and reclamation of the site as BLM requires.

Permittee means any Federal, State, or territorial agency, unit, or subdivision, including municipalities, or any non-profit organization, to which BLM issued a free use permit for the removal of mineral materials from the public lands.

Public lands means any lands and interest in lands owned by the United States and administered by the Secretary of the Interior through BLM

without regard to how the United States acquired ownership, except lands held for the benefit of Indians, Aleuts, and Eskimos.

Purchaser means any person, including a business or government entity, buying or holding a contract to purchase mineral materials on the public lands.

§ 3601.6 Policy.

It is BLM's policy:

(a) To make mineral materials available unless it is detrimental to the public interest to do so;

(b) To sell mineral material resources at not less than fair market value;

(c) To permit Federal, State, Territorial, and local government entities and non-profit organizations free use of these materials for qualified purposes;

(d) To protect public land resources and the environment and minimize damage to public health and safety during the exploration for and the removal of such minerals;

(e) To prevent unauthorized removal of mineral materials; and

(f) To require purchasers and permittees to account for all removals of mineral materials.

§ 3601.8 Public availability of information.

(a) All data and information concerning Federal and Indian minerals that you submit under this part are subject to part 2 of this title. Part 2 of this title includes the regulations of the Department of the Interior covering the public disclosure of data and information contained in Department of the Interior records. BLM may make available for inspection certain mineral information not protected from disclosure under part 2 of this title without a Freedom of Information Act (FOIA) (5 U.S.C. 552) request.

(b) When you submit data and information under this part that you believe to be exempt from public disclosure, and that you wish BLM to withhold from such disclosure, you must clearly mark each page that you believe includes confidential information. BLM will keep all data and information confidential to the extent allowed by § 2.13(c) of this title.

§ 3601.9 Information collection.

The Office of Management and Budget has approved the information collection requirements in part 3600 under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1004–0103. BLM is collecting the information to allow us to determine if you are qualified to purchase or have free use of mineral materials on the public lands. You must respond to obtain a benefit.

Limitations on Disposal of Mineral Materials

§ 3601.10 Limitations on BLM's discretion to dispose of mineral materials.

§ 3601.11 When will environmental considerations prevent BLM from disposing of mineral materials?

BLM will not dispose of mineral materials if we determine that the aggregate damage to public lands and resources would exceed the public benefits that BLM expects from the proposed disposition.

§ 3601.12 What areas does BLM exclude from disposal of mineral materials?

(a) BLM will not dispose of mineral materials from wilderness areas or other areas where it is expressly prohibited by law. This includes national parks and monuments.

(b) BLM will not dispose of mineral materials from Indian lands and lands set aside or held for the use or benefit of Indians.

(c) BLM will not dispose of mineral materials from areas identified in land use plans as not appropriate for mineral materials disposal.

§ 3601.13 How can I obtain mineral materials from Federal lands that have been withdrawn to aid a function of another Federal agency or of a State or local government agency?

If you wish to obtain mineral materials from lands withdrawn to aid a function of another Federal agency or of a State or local government agency, you may apply to BLM. BLM will dispose of the mineral materials only with the consent of that agency.

§ 3601.14 When can BLM dispose of mineral materials from unpatented mining claims?

(a) BLM may dispose of mineral materials from unpatented mining claims if disposal does not endanger or materially interfere with prospecting, mining, or processing operations, or uses reasonably incident thereto.

(b) BLM will ask a mining claimant for a waiver before disposing of mineral materials from a claim. If the mining claimant refuses to sign a waiver, BLM will make sure that disposal of the mineral materials will not be detrimental to the public interest. We also will consult with the Solicitor's Office, if necessary, before proceeding with the disposal.

Rights of Purchasers and Permittees

§ 3601.20 Rights of parties.

§ 3601.21 What rights does a person have under a materials sales contract or use permit?

(a) Unless otherwise provided, if you are a purchaser under a sales contract or a free use permittee, you have the right to:

(1) Extract, remove, process, and stockpile the material until the contract or permit terminates, regardless of any rights others acquire later under the provisions of the general land laws; and

(2) Use and occupy the described lands to the extent necessary for fulfillment of the contract or permit.

(b) Users of the lands covered by your materials sales contract or free use permit who acquire their rights later than the date BLM designated the tract for mineral materials disposal will be subject to your existing use authorization, as provided in § 3602.12. This applies to uses due to any later settlement, location, lease, sale, or other appropriation under the general land laws, including the mineral leasing and mining laws.

§ 3601.22 What rights remain with the United States when BLM sells or issues a permit for mineral materials?

Your sale contract or use permit is subject to the continuing right of the United States to issue leases, permits, and licenses for the use and occupancy of the lands, if such use would not endanger or materially interfere with the production or removal of materials under contract or permit.

Pre-Application Sampling and Testing

§ 3601.30 Pre-application activities—how and when may I sample and test mineral materials?

(a) BLM may authorize you in writing to sample and test mineral materials. The authorization letter expires after 90 days, but BLM may extend it for an additional 90 days if you show us that an extension is necessary. BLM may authorize these activities before issuing a sales contract or free use permit.

(b) You must submit your sampling and testing findings to BLM. All information you submit under this section is subject to part 2 of this title. That part sets forth the rules of the Department of the Interior relating to public availability of information contained in Departmental records. (*See* § 3601.8.)

(c) A letter from BLM authorizing you to sample and test mineral materials does not give you a preference right to a sales contract or free use permit.

(d) BLM may impose bonding and reclamation requirements on sampling and testing that you conduct under an authorization letter.

Mining and Reclamation Plans

§ 3601.40 Mining and reclamation plans.

BLM may require you to submit mining and reclamation plans before we begin any environmental review or issue a contract or permit. You may combine these plans in one document.

§ 3601.41 What information must I include in my mining plan?

If BLM requires you to submit a mining plan, it must include:

(a) A map, sketch, or aerial photograph identifying the area for which you are applying, the area and depth you plan to disturb, existing and proposed access, and the names and locations of major topographic and known cultural features;

(b) A description of your proposed methods of operation and the periods during which you will operate;

(c) A description of measures you will take to prevent hazards to public health and safety and to minimize and mitigate environmental damage; and

(d) Such other information as BLM may require.

§ 3601.42 What information must I include in my reclamation plan?

If BLM requires you to submit a reclamation plan, it must include:

(a) A statement of the proposed manner and time in which you will complete reclamation of the areas disturbed by your operations;

(b) A map or sketch which delineates the area you will reclaim; and

(c) Such other information as BLM may require.

§ 3601.43 What is the process for BLM to approve my mining and reclamation plans?

(a) After reviewing your mining and reclamation plans, BLM will notify you of any deficiencies in the plans and recommend the changes necessary. BLM will notify you in writing when we approve your plan. You must follow BLM-approved mining and reclamation plans, which become part of the contract or permit.

(b) Your operation must not deviate from the plan BLM approves, unless it is modified under § 3601.44.

§ 3601.44 How and when may my mining or reclamation plan be modified?

(a) Either you or BLM may initiate a modification of an approved mining or reclamation plan to adjust for changed conditions or to correct any oversight. BLM will consult with you before requiring a modification.

(b) If BLM notifies you that you must modify your plan, you must prepare the modification, or explain why you need more time, within 30 days. If you fail to modify your plan to BLM's satisfaction, BLM may order you to stop operations under your contract or permit.

(c) When you ask to change an approved mining or reclamation plan for one of the reasons in paragraph (a) of this section, BLM will notify you in writing within 30 days whether we approve the modification, deny it, or require any changes in it.

Contract and Permit Administration

§ 3601.50 Administration of sales contracts and free use permits.

§ 3601.51 How will BLM inspect my operation?

You must allow BLM access at any reasonable time:

(a) To inspect or investigate the mine condition;

(b) To conduct surveys;

(c) To estimate the volume, types, and composition of commodities that you mine or remove;

(d) To examine weight tickets, truck logs, and other records that BLM finds necessary to verify production; and

(e) To determine whether you comply with contract, permit, statutory, or regulatory requirements.

§ 3601.52 After I finish my operations, when must I remove improvements and equipment?

After your contract or permit period expires, or after cancellation of your permit or contract, BLM will allow you up to 90 days, excluding periods of inclement weather, to remove the equipment, personal property, and any other improvements that you placed on the public lands. You may leave in place improvements such as roads, culverts, and bridges if BLM consents. If you fail to remove equipment, personal property, or any other improvement, it becomes the property of the United States. However, you remain liable for the cost of its removal and for restoration of the site.

Contract and Permit Cancellation

§ 3601.60 Cancellation.

§ 3601.61 When may BLM cancel my contract or permit?

BLM may cancel your contract or free use permit if you:

(a) Fail to comply with the provisions of the Materials Act of 1947, as amended (30 U.S.C. 601 *et seq.*);

(b) Fail to comply with any applicable regulations; or

(c) Default in the performance of any material term, covenant, or stipulation in the contract.

§ 3601.62 Cancellation procedure.

(a) BLM will give you written notice of any defaults, breach, or cause of forfeiture, either in person or by certified mail. You have 30 days after receiving the notice:

(1) To correct all defaults;

(2) To request an extension of time in which to correct the defaults; or

(3) To submit evidence showing to BLM's satisfaction why we should not cancel your contract or free use permit.

(b) If you fail to respond to the notice under paragraph (a) of this section, or if delivery of the notice is refused, or not completed as described in § 1810.2 of this chapter, BLM may cancel the contract or permit.

Unauthorized Use

§ 3601.70 Unauthorized use.

§ 3601.71 What constitutes unauthorized use?

(a) Except as provided in paragraph (b) of this section, you must not extract, sever, or remove mineral materials from public lands under the jurisdiction of the Department of the Interior, unless BLM or another Federal agency with jurisdiction authorizes the removal by sale or permit. Violation of this prohibition constitutes unauthorized use.

(b) If you own the surface estate of lands with reserved Federal minerals, you may use mineral materials within the boundaries of your surface estate without a sales contract or permit only in the following circumstances:

(1) You use a minimal amount of mineral materials for your own personal use;

(2) You have statutory authority to use the mineral materials; or

(3) You have other express authority to use the mineral materials.

§ 3601.72 What are the consequences of unauthorized use?

Unauthorized users are liable for damages to the United States, and are subject to prosecution for such unlawful acts (see subpart 9239 of this chapter).

Appeals

§ 3601.80 How do I appeal a final decision by BLM?

If a BLM decision adversely affects you, you may appeal the decision in accordance with parts 4 and 1840 of this title.

Subpart 3602—Mineral Materials Sales

Applications

§ 3602.10 Applying for a mineral materials sales contract.

§ 3602.11 How do I request a sale of mineral materials?

(a) You may submit a written request for sale of mineral materials to the BLM office with jurisdiction over the site containing the materials. No particular form is required for this request.

(b) BLM also may initiate a sale without a request under paragraph (a) of this section.

§ 3602.12 How does the mineral materials sales process affect other users of the same public lands?

(a) When BLM designates tracts for competitive or noncompetitive sale of mineral materials, and notes the designation in the public land records, it creates a right to remove the materials superior to any subsequent claim, entry, or other conflicting use of the land, including subsequent mining claim locations.

(b) The superior right under paragraph (a) of this section is part of all contracts and permits BLM authorizes within 2 years after the date we designate the tract. BLM may extend this 2–year period for one additional year for good cause. The right continues for the entire term of the contract or permit and any renewal term. The superior right under paragraph (a) of this section also applies to any subsequent contracts or permits that BLM authorizes within 2 years after the previous contract or permit expires or terminates.

(c) This right does not prevent other uses or segregate the land from the operation of the public lands laws, including the mining and mineral leasing laws. However, such subsequent uses must not interfere with the extraction of mineral materials.

§ 3602.13 How does BLM measure and establish the price of mineral materials?

(a) BLM will not sell mineral materials at less than fair market value. BLM determines fair market value by appraisal.

(b) BLM may periodically reappraise the value of mineral materials not yet removed, and adjust your contract price accordingly. BLM will not adjust the price during the first 2 years of the contract. BLM also will not adjust the contract price during the 2–year period following any adjustment. However, BLM may adjust the price at the beginning of any contract renewal period.

(c) BLM measures mineral materials by in-place volume or weight equivalent. When BLM requires you to measure materials, we may either designate the method you must use or allow you to choose either method. We will verify your results.

§ 3602.14 What kind of financial security does BLM require?

(a) For contracts of $2,000 or more, BLM will require a performance bond of an amount sufficient to meet the reclamation standards provided for in the contract, but at least $500. If you have a sales contract from a community pit or common use area and you pay a reclamation fee, BLM will not require you to post a performance bond.

(b) BLM may require a performance bond for contracts of less than $2,000. We will not require a bond amount greater than 20 percent of the total contract value.

(c) A performance bond may be a—

(1) Bond of a corporate surety shown on the approved list (Circular 570) issued by the U.S. Treasury Department, including surety bonds arranged or paid for by third parties;

(2) Certificate of deposit that:

(i) Is issued by a financial institution whose deposits are Federally insured;

(ii) Does not exceed the maximum insurable amount set by the Federal Deposit Insurance Corporation;

(iii) Is made payable or assigned to the United States;

(iv) Grants BLM authority to demand immediate payment if you fail to meet the terms and conditions of the contract;

(v) States that no party may redeem it before BLM approves its redemption; and

(vi) Otherwise conforms to BLM's instructions as found in the contract terms;

(3) Cash bond, with a power of attorney to BLM to convert it upon your failure to meet the terms and conditions of the contract;

(4) Irrevocable letter of credit from a bank or financial institution organized or authorized to transact business in the United States, with a power of attorney to BLM to redeem it upon your failure to meet the terms and conditions of the contract; or

(5) Negotiable Treasury bond of the United States of a par value equal to the amount of the required bond, together with a power of attorney to BLM to sell it upon your failure to meet the terms and conditions of the contract.

§ 3602.15 What will happen to my bond if I transferred all of my interests or operations to another bonded party?

BLM will cancel your bond obligations following approval of the transfer of your interests or operations if the transferee provides a bond that assumes all of your existing liabilities as required in § 3602.24. However, under § 3602.26, you remain liable for any reclamation or other obligation that accrued during the time you held your interest.

Administration of Sales

§ 3602.20 Administration of mineral materials sales.

§ 3602.21 What payment terms apply to my mineral materials sales contract?

(a) Under a sales contract for mineral materials—

(1) For sales of $2,000 or less, you must pay the full amount before BLM will sign the contract.

(2) When the sale exceeds $2,000, you may make installment payments. The first installment payment must be the greater of $500 or 5 percent of the total purchase price. If you elect to make installment payments—

(i) For non-competitive sales, you must pay the first installment at or before the time BLM awards the contract;

(ii) For competitive sales, you must pay the first installment as a deposit at the time you submit the bid; and

(iii) For noncompetitive and competitive sales—

(A) Once you have removed materials, you must make each subsequent installment payment monthly in an amount equal to the value of the minerals you remove each month. You must make the payment by the 15th day following the end of the month for which you are reporting. However, you must pay the balance of the purchase price not later than 60 days before the expiration date of the contract. BLM will credit your first installment payment to you at the time of your final payment unless we cancel your contract under § 3601.61; or

(B) You may make advance payment for your annual production based on the previous year's production or your projection of the current year's production, so long as you resume paying on a monthly basis as required in paragraph (a)(2)(iii)(A) of this section if your annual payment does not cover your actual production for the current year. You must resume monthly payments no later than the 15th day following the end of the month in which production exceeds the projected production on which payments were based.

(3) You must annually (as provided in your contract) produce an amount sufficient to pay to the United States a sum of money equal to the first

installment determined under paragraph (a)(2) of this section. In lieu of such production, you may make an annual payment in the amount of the first installment. If in any contract year you make production payments that are less than the first installment, you must pay the difference between the production payments and the amount of the first installment. These annual payments are due on or before each anniversary date of the contract.

(b) If you fail to comply with the terms and conditions of the contract and BLM cancels your contract under § 3601.61, you will forfeit all moneys that you paid.

§ 3602.22 When will a contract terminate?

(a) Your contract terminates when—

(1) Its term expires;

(2) You have completed production under your contract or permit and any renewal, and completed required reclamation; or

(3) BLM cancels your contract under § 3601.60 *et seq.* of this part.

(b) You and BLM may, by agreement, terminate the sales contract at any time.

§ 3602.23 When will BLM make refunds or allow credits?

(a) BLM may make refunds or allow credits if—

(1) When your contract expires, your total payments exceed the total value of mineral materials included in the contract;

(2) BLM determines that insufficient mineral materials existed in the sales area to fulfill the terms of the contract; or

(3) Materials you paid for are unavailable as a result of terminating your contract by mutual agreement under § 3602.22(b).

(b) If your refund or credit is a result of terminating your contract by mutual agreement under § 3602.22(b), BLM will reduce the amount of the refund or credit by the amount of the administrative cost of processing the disposal action. If these administrative costs exceed your total payments, BLM will not make a refund or allow a credit.

(c) BLM may credit to future production on the same contract, but not refund, payments that you make in lieu of production under § 3602.21(a)(3). However, if, upon expiration of the contract, the total value of payments you have made exceeds the total value of mineral materials included in your contract, BLM will refund the difference in accordance with paragraphs (a) and (b) of this section.

§ 3602.24 When may I assign my materials sales contract?

(a) You may not assign the contract or any interest therein unless BLM approves the transfer in writing.

(b) BLM will not approve your proposed assignment of contract, unless—

(1) Your assignee—

(i) Furnishes a financial guarantee as required by § 3602.14; or

(ii) Obtains a written commitment from the previous surety that it will be bound by the assignment when BLM approves it; and

(2) The assignment contains all the terms and conditions in your contract.

§ 3602.25 What rights and responsibilities does my assignee assume?

When BLM approves your assignment, your assignee is entitled to all the rights and is subject to all the obligations under the contract.

§ 3602.26 If I assign my contract, when do my obligations under the contract end?

When BLM approves your assignment, you are released from any further liability under the contract for actions the assignee may take after the effective date of the assignment. You continue to be responsible for obligations that accrued before the approval date, whether or not you knew of them at the time of the transfer.

§ 3602.27 When will BLM extend the term of a contract?

BLM may grant a one-time extension of the contract not to exceed 1 year, if:

(a) (1) For contracts with terms over 90 days, BLM receives your written request between 30 and 90 days before the contract expires; or

(2) For contracts with terms of 90 days or less, BLM receives your written request not later than 15 days before the contract expires; and

(b) You show in writing that the delay in removing the mineral materials was due to causes beyond your control and was not due to your fault or negligence.

§ 3602.28 What records must I maintain and how long must I keep them?

(a) BLM may require you to maintain and preserve for 6 years records, maps, and surveys relating to production verification and valuation. These include, but are not limited to, detailed records of quantity, types, and value of commodities you moved, processed, sold, delivered, or used.

(b) You must make such records available to BLM to allow us to determine whether you have complied with statutes, regulations, and the terms of the contract.

§ 3602.29 How will BLM verify my production?

(a) You must submit at least one report per contract year of the amount of mineral materials you have mined or removed under your sales contract so BLM can verify that you have made the required payments. BLM will specify the timing of the reports in your contract or permit.

(b) BLM may require more frequent reporting if we find it necessary.

(c) BLM may require you to conduct pre-operation, annual, and post-operation volumetric surveys of the mine site.

Noncompetitive Sales

§ 3602.30 Noncompetitive sales.

In addition to the following sections, §§ 3602.31 through 3602.35, the provisions of §§ 3602.11 through 3602.29 also apply to noncompetitive sales.

§ 3602.31 What volume limitations generally apply to noncompetitive mineral materials sales?

(a) BLM may sell, at not less than fair market value, and without advertising or calling for bids, mineral materials not greater than 200,000 cubic yards (or weight equivalent) in any individual sale, when BLM determines it to be:

(1) In the public interest; and

(2) Impracticable to obtain competition.

(b) BLM will not approve multiple noncompetitive sales that exceed a total of 300,000 cubic yards (or weight equivalent) made in any one State for the benefit of any one purchaser, whether an individual, partnership, corporation, or other entity, in any period of 12 consecutive months.

(c) The volume limitations in paragraphs (a) and (b) of this section do not apply to sales in the State of Alaska that BLM determines are needed for construction, operation, maintenance, or termination of the Trans-Alaska Pipeline System or the Alaska Natural Gas Transportation System.

(d) The volume limitations in paragraphs (a) and (b) of this section do not apply if:

(1) BLM determines that circumstances make it impossible to obtain competition; or

(2) There is insufficient time to invite competitive bids, because of an emergency situation affecting public property, health, or safety.

§ 3602.32 What volume and other limitations pertain to noncompetitive sales associated with public works projects?

BLM may sell mineral materials not exceeding 400,000 cubic yards (or

weight equivalent), at not less than fair market value, without advertising or calling for bids if:

(a) BLM determines the sale to be in the public interest; and

(b) The materials will be used in connection with an urgent public works improvement program on behalf of a Federal, State, or local governmental agency, and time does not permit advertising for a competitive sale.

§ 3602.33 How will BLM dispose of mineral materials for use in developing Federal mineral leases?

(a) If you propose to use mineral materials in connection with developing a mineral lease issued by BLM, we may, without calling for competitive bids, sell you at fair market value a volume of mineral materials not exceeding a total of 200,000 cubic yards (or weight equivalent) in one State in any period of 12 consecutive months.

(b) If the materials remain within the boundaries of the lease, BLM will not charge for mineral materials that you must move in order to extract minerals under a Federal lease, whether or not you use them for lease development.

§ 3602.34 What is the term of a noncompetitive contract?

BLM will not issue a noncompetitive contract for the sale of mineral materials for a term exceeding 5 years, excluding any contract extension under § 3602.27 and any period that BLM may allow for removal of equipment and improvements under § 3601.52.

Competitive Sales

§ 3602.40 Competitive sales.

In addition to the following sections, §§ 3602.41 through 3602.49, the provisions of §§ 3602.11 through 3602.29 also apply to competitive sales.

§ 3602.41 When will BLM sell mineral materials on a competitive basis?

Except for sales from community pits and common use areas under subpart 3603 of this part, and noncompetitive sales under § 3602.30 *et seq.*, BLM will make sales only after inviting competitive bids through publication and posting under § 3602.42.

§ 3602.42 How does BLM publicize competitive mineral materials sales?

(a) When offering mineral materials for sale by competitive bidding, BLM:

(1) Will advertise the sale by publishing a sale notice in a newspaper of general circulation in the area where the material is located, on the same day once a week for 2 consecutive weeks; and

(2) Will post a sale notice in a conspicuous place in the office where you will submit bids.

(b) In the sale notice, BLM will state:

(1) By legal description, the location of the tract or tracts on which we are offering the materials;

(2) The kind of materials we are offering;

(3) The estimated quantities of materials we are offering;

(4) The unit of measurement;

(5) The appraised prices;

(6) The time and place for receiving and opening of bids;

(7) The minimum deposit we require;

(8) The site access that will be available to the purchaser;

(9) The method of bidding;

(10) If applicable, that the purchaser must file mining or reclamation plans;

(11) The bonding requirement;

(12) The location for inspection of contract terms and proposed stipulations;

(13) The address and telephone number of the office where you may obtain additional information;

(14) Whether BLM will renew the contract; and

(15) Any additional information that BLM deems necessary.

(c) BLM may, in its discretion, extend the period of time for advertising;

(d) BLM will not hold sales sooner than 1 week after the last advertisement.

§ 3602.43 How does BLM conduct competitive mineral materials sales?

(a) In conducting a competitive sale, BLM may require submission of sealed written bids, oral bids, or a combination of both. The sale notice will state how you must submit your bid. If 2 or more persons make identical high sealed bids, BLM will determine the highest bid by holding an oral auction among the persons making the identical high bids. If no oral bid is made higher than the sealed bids, BLM will pick the successful bidder by lot. After BLM announces the high bid at an oral auction, if you are the high bidder you must confirm that bid in writing at least by the close of business on the date of the sale, or by such time as BLM may specify in the sale notice.

(b) When BLM determines that it is in the public interest to do so, we may reject any or all bids, or may waive minor deficiencies in the bids that would not ordinarily affect the outcome of the bidding.

§ 3602.44 How do I make a bid deposit?

(a) If you wish to make a bid to purchase mineral materials, you must submit a deposit in advance of the sale.

(1) Your sealed bids must contain a deposit.

(2) At an oral auction, you must make your deposit before the opening of the bidding.

(b) Your deposit must be the greater of $500 or 5 percent of the appraised value as we specify in the sale notice.

(c) Your deposit may be in the form of cash, a money order, a bank draft, or a cashier's or certified check made payable to the Bureau of Land Management.

(d) If you are not the successful bidder, BLM will return your bid deposit when the bidding concludes.

(e) If you are the successful bidder, BLM will apply your deposit to the purchase price.

§ 3602.45 What final steps will BLM take before issuing me a contract?

(a) *Ability to perform.* BLM may require you to furnish information we find necessary to determine whether you are able to meet the obligations of the contract.

(b) *Reasons for denying a contract.* We will deny you the contract, even if you made the highest bid, if—

(1) We determine that you are unable to meet the obligations of the contract,

(2) You are unwilling to accept the terms of the contract, or

(3) BLM rejects all bids.

(c) *Refund of deposit.* If BLM denies you a contract under paragraph (b)(1) or (b)(3) of this section, we will refund your deposit.

(d) *Awarding a contract.* BLM will notify you of your contract award by presenting you with or sending you the contract.

(e) *Accepting a contract.* If BLM awards you the contract, you must, within 60 days after receiving it, sign and return the contract, together with a performance bond and mining and reclamation plan when BLM requires them. BLM may extend this period an additional 30 days if you request it in writing within the first 60-day period. If you fail to sign and return the contract within the first 60-day period, or an approved 30-day extension period, you will forfeit the bid deposit.

(f) *Awarding the contract to the second-highest bidder.* If BLM determines that you are unable to meet the obligations of the contract, or if you fail to sign and return the contract within the time period specified, BLM may offer and award the contract for the amount of the high bid to the person making the next highest complete bid. That person must be qualified and willing to accept the contract, and must redeposit the amount required under § 3602.44(b).

(g) *Contract form.* BLM will make all sales on BLM standard contract forms

approved by the Director, Bureau of Land Management. We will include as necessary additional provisions and stipulations in the contract to conform to the provisions of the competitive sale notice and to address environmental concerns or other site-specific issues.

§ 3602.46 What is the term of a competitive contract?

The term of the contract will be in the sales notice. BLM will not issue a competitive contract for the sale of mineral materials for a term exceeding 10 years. However, the 10-year period does not include any contract extension under § 3602.27, any contract renewal under § 3602.47, and any periods for removal of equipment and improvements under § 3601.52 of this part.

§ 3602.47 When and how may I renew my competitive contract?

(a) *Applying for competitive contract renewal.* When you have paid the United States the full contract price for the mineral materials you purchased under a competitive contract, you may apply for renewal of the contract without further competitive bidding in order to purchase and extract additional material that may be available at the contract site. You must submit your request for renewal of the contract at least 90 days before it expires. You do not need to use a specific form.

(b) *BLM's response to the application.* BLM will renew your contract if—

(1) You meet all the requirements of this section;

(2) Your contract is not limited under § 3602.49; and

(3) BLM determines that you are able to fulfill the obligations of a new contract.

(c) *Renewal term.* BLM will renew your contract for a maximum term of 10 additional years. The renewal may be for less than 10 years if you do not request that much time, or if BLM finds that the quantity of material involved does not justify a 10-year term.

(d) *Number of times BLM may renew a contract.* There is no maximum number of times BLM may renew a contract.

§ 3602.48 What may BLM require when renewing my contract?

(a) *Reappraisal.* BLM will not grant a renewal without requiring a reappraisal under § 3602.13.

(b) *Bond amount and terms.* Before renewing your contract, BLM may require you to increase, or allow you to decrease, the amount of the performance bond you posted under § 3602.14. BLM may also require other bond modifications to ensure coverage for the renewed contract.

(c) *Environmental protection requirements.* Before renewing your contract, BLM will perform additional environmental analysis as required, and may require you to adopt additional measures to prevent hazards to public health and safety, and to minimize and mitigate environmental damage.

(d) *Other requirements.* BLM may require additions or changes to other terms or conditions of your contract.

§ 3602.49 When will BLM issue a non-renewable contract?

(a) BLM may offer you a contract restricted to a single term or otherwise limited in its duration. We will base this restriction on a finding that—

(1) The land should be used for another, possibly conflicting, purpose after mineral materials are removed;

(2) The deposit of mineral materials may be appropriate for future use by multiple operators or by the local community; or

(3) Other circumstances make renewal inappropriate.

(b) If BLM limits a contract under this section, the sale notice under § 3602.42 will include this information.

(c) If your contract is in existence on December 24, 2001, BLM will decide whether you may request renewal of that contract. You must ask BLM for this decision at least 90 days before the contract expires. If fewer than 120 days remain on your existing contract on December 24, 2001, BLM may approve a renewal request that you submit less than 90 days before the contract expires if we decide the contract qualifies for renewal and we have sufficient time to process your request before your contract is due to expire.

Subpart 3603—Community Pits and Common Use Areas

Disposal of Materials—Community Pits and Common Use Areas

§ 3603.10 Disposal of mineral materials from community pits and common use areas.

(a) BLM may make mineral material sales and allow free use under permit from the same deposit within areas that we designate for this purpose. These kinds of disposals must be consistent with other provisions of this part. These designated community pit sites or common use areas may be any size.

(b) This subpart applies to both sales and free use from community pits and common use areas unless otherwise stated. Refer to subpart 3604 of this part for additional regulations applicable to the free use of mineral materials.

§ 3603.11 What rights pertain to users of community pits?

BLM's designation of a community pit site, when noted on the appropriate BLM records or posted on the ground, establishes a right to remove the materials superior to any subsequent claim or entry of the lands.

§ 3603.12 What rights pertain to users of common use areas?

(a) BLM's designation of a common use area does not establish a right to remove the materials superior to any subsequent claim or entry of the lands.

(b) Once you have a permit or a sales contract to remove mineral materials from a common use area, your rights under that permit or contract are superior to any subsequent claim or entry on the lands.

§ 3603.13 What price does BLM charge under materials sales contracts for mineral materials from community pits and common use areas?

BLM will sell mineral materials from community pits or common use areas under materials sales contracts for not less than fair market value.

§ 3603.14 What plans do I need to prepare to mine or remove mineral materials from a community pit or common use area?

BLM generally will not require a mining or reclamation plan before you mine or remove mineral materials from a community pit or common use area. We may require such a plan if we find that circumstances warrant it. In all cases, you must comply with the terms of the contract or permit to protect health, safety, and the environment.

Reclamation

§ 3603.20 Reclamation.

§ 3603.21 What reclamation requirements pertain to community pits and common use areas?

Generally, you do not need to perform reclamation after extracting mineral materials from community pits or common use areas. However, you must pay a reclamation fee as provided in § 3603.22.

§ 3603.22 What fees must I pay to cover the cost of reclamation of community pits and common use areas?

(a) You must pay a reclamation fee based on the amount of mineral materials you extract from the community pit or common use area, unless you make an alternative arrangement under paragraph (b) of this section. The reclamation fee you pay is a proportionate share of the total estimated cost of reclamation, determined by using the ratio of the material that you extract under your

permit or contract to the total volume of the material BLM estimates will be extracted from the site.

(b) BLM may, at our discretion, allow purchasers and permittees to perform interim or final reclamation, where needed, in lieu of paying reclamation charges. If BLM allows you to perform reclamation in lieu of paying a fee, we may also require you to post a bond under § 3602.14.

Subpart 3604—Free Use of Mineral Materials

Obtaining Free Use Permits

§ 3604.10 Permits for free use of mineral materials.

§ 3604.11 How do I apply for a free use permit?

If you wish to apply for free use of mineral materials, you may file a letter of request or a BLM standard application form approved by the Office of Management and Budget.

§ 3604.12 Who may obtain a free use permit?

Any Federal, State, or territorial agency, unit, or subdivision, including municipalities, or any non-profit organization, may apply for a free use permit to extract and use mineral materials.

(a) BLM may issue free use permits to a government entity without limitation as to the number of permits or as to the value of the mineral materials to be extracted or removed, provided that the government entity shows that it will not use these materials for commercial or industrial purposes.

(b) BLM may issue free use permits to a non-profit organization for not more than 5,000 cubic yards (or weight equivalent) in any period of 12 consecutive months, provided that the organization shows that it will not use these materials for commercial or industrial purposes.

§ 3604.13 When will BLM decline to issue a free use permit to a qualified applicant?

BLM will not issue a free use permit if we determine that you own or control an adequate supply of suitable mineral materials that:

(a) Are readily available, and

(b) You can mine in a manner that is economically and environmentally acceptable.

Administration of Free Use

§ 3604.20 Administration of free use permits.

§ 3604.21 What is the term of a free use permit?

(a) BLM will determine the appropriate length of your free use permit term.

(1) BLM will not grant free use permits to government entities for terms exceeding 10 years.

(2) BLM will not grant free use permits to non-profit organizations for terms exceeding one year.

(b) BLM may extend any free use permit term for a single additional period not to exceed one year.

§ 3604.22 What conditions and restrictions pertain to my free use permit?

(a) You must not barter or sell mineral materials that you obtain under a free use permit.

(b) You must not remove mineral materials before BLM issues you a permit or after your permit expires.

(c) BLM may incorporate other conditions and restrictions into your free use permit.

§ 3604.23 When and how may I assign my free use permit?

You may assign or transfer your free use permit to entities qualified under § 3604.12. You must first obtain BLM's written approval.

§ 3604.24 Who may remove materials on my behalf?

(a) You may allow your agent to extract mineral materials under your free use permit.

(b) Your agent may charge you only for extraction services and must not—

(1) Charge you for the materials extracted, processed, or removed; or

(2) Take mineral materials from the permit area as payment for services rendered to you, or as a donation or gift.

§ 3604.25 What bond requirements pertain to free use permits?

BLM may require a bond or other security as a guarantee of your faithful compliance with the provisions of your permit and applicable regulations, including reclamation. The type of security must be one of those provided for in § 3602.14(c) of this part.

§ 3604.26 When will BLM cancel my permit?

BLM may cancel your permit if you fail, after adequate notice, to follow its terms and conditions.

§ 3604.27 What rights does a free use permit give me against other users of the land?

Permits that BLM issues under this subpart constitute a superior right to remove the materials in accordance with the permit terms and provisions, as against any claim to or entry of the lands made after the date BLM designated the tract for mineral materials disposal. *See* § 3602.12.

PART 3610—[REMOVED]

2. Part 3610 is removed.

PART 3620—FREE USE OF PETRIFIED WOOD

3. The authority citation for part 3620 is revised to read as follows:

Authority: 30 U.S.C. 601 *et seq.*; 43 U.S.C. 1201, 1732, 1733, 1740; Sec. 2, Act of September 28, 1962 (Pub. L. 87–713, 76 Stat. 652).

4. The heading of part 3620 is revised to read as set forth above.

5. Subpart 3621 consisting of §§ 3621.1 through 3621.7 and 3621.2, is removed.

Subpart 3622—Free Use of Petrified Wood

6. Section 3622.1 is amended by revising paragraph (b) to read as follows:

§ 3622.1 Program: General.

* * * * *

(b) The purchase of petrified wood for commercial purposes is provided for in § 3602.10 *et seq.* of this chapter.

7. Section 3622.2 is amended by removing the phrase ''subpart 3621 of this title'' from the second sentence and adding in its place the phrase ''subpart 3604 of this chapter.''

8. Section 3622.4 is amended by:

a. Removing the phrase ''subpart 3621 of this title'' from paragraph (a)(2) and adding in its place the phrase ''subpart 3604 of this chapter,''

b. Removing the phrase ''unnecessary and undue degradation of lands'' from paragraph (a)(4) and adding in its place the phrase ''hazards to public health and safety, and minimizes and mitigates environmental damage.''

c. Removing the phrase ''in § 3622.4(a) of this title'' at the end of paragraph (b), and adding in its place the phrase ''in paragraph (a) of this section.''

PART 3800—MINING CLAIMS UNDER THE GENERAL MINING LAWS

Subpart 3809—Surface Management

9. The authority citation for part 3800 continues to read as follows:

Authority: 16 U.S.C. 1280; 30 U.S.C. 22; 30 U.S.C. 612; 43 U.S.C.1201; and 43 U.S.C. 1732, 1733, 1740, 1781, and 1782.

10. Section 3809.101 is amended by revising paragraph (d) to read as follows:

§ 3809.101 What special provisions apply to minerals that may be common variety minerals, such as sand, gravel, and building stone?

* * * * *

(d) *Disposal.* BLM may dispose of common variety minerals from unpatented mining claims in accordance with the provisions of § 3601.14 of this chapter.

[FR Doc. 01–29001 Filed 11–21–01; 8:45 am]

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Federal Register

Friday,
November 23, 2001

Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Parts 121, 125, et al.
Service Difficulty Reports; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125, 135, and 145

[Docket No. FAA–2000–7952]

RIN 2120–AF71

Service Difficulty Reports

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; delay of effective date.

SUMMARY: The Federal Aviation Administration (FAA) is further delaying the effective date of a final rule that amends the reporting requirements for air carriers and certificated domestic and foreign repair station operators concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and components. This action is prompted by concerns the aviation industry raised about the reporting requirements in the final rule and the FAA's decision to issue a notice of proposed rulemaking (NPRM) to address these concerns. The NPRM will present the FAA's proposal on how the agency intends to amend the final rule. Delaying the effective date of the final rule will allow additional time for completion of the NPRM process.

DATES: The effective date of the rule amending 14 CFR parts 121, 125, 135, and 145 published at 65 FR 56191, September 15, 2000, and delayed at 65 FR 80743, December 22, 2000 and at 66 FR 21626, April 30, 2001 until January 16, 2002, is further delayed until January 16, 2003.

FOR FURTHER INFORMATION CONTACT: Jose Figueroa, AFS–300, Federal Aviation Administration, 800 Independence Ave. SW, Washington, DC 20591, 202–267–3797.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 2000, the FAA requested comments on the information collection requirements on the final rule entitled ''Service Difficulty Reports'' (65 FR 56191). That final rule, which had an effective date of January 16, 2001, amended the reporting requirements for air carriers and certified domestic and foreign repair station operators concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and components. The FAA received extensive written comments on the Service Difficulty Reporting (SDR) requirements and on the potential duplicate reporting of certain failures, malfunctions, and defects. On November 30, 2000, the FAA announced (65 FR 71247) that a public meeting on this rulemaking would be held on December 11, 2000. Participants at that meeting raised novel issues that the FAA was not aware of when preparing the final rule.

As a result of the concerns expressed at the meeting and those raised during the comment period for the final rule (published September 15, 2000), the FAA delayed the effective date of the final rule in two subsequent notices. The purpose of these delays was to allow the agency time to consider industry's concerns. The first notice (65 FR 80743) was published on December 22, 2000, and the second notice (66 FR 21626) was published on April 30, 2001. The FAA now anticipates that it will issue an NPRM to address the issues raised and to give the aviation industry and the general public the opportunity to comment on the agency's proposed revisions to the final rule. To allow time to proceed with the NPRM process, the FAA further extends the effective date of the final rule until January 16, 2003. The FAA cautions the industry that the existing rules will remain in effect until the new effective date.

Since the delay in the effective date of the final rule does not impose any new requirements or any additional burden on the regulated public, the FAA finds that good cause exists for immediate adoption of the new effective date without a 30-day notice.

Please note that the FAA transitioned to a new Docket Management System maintained by the Department of Transportation during the course of the SDR rulemaking. The docket number for this rulemaking is now ''FAA–2000–7952.'' At earlier stages of the rulemaking, the docket number was ''28293.''

Issued in Washington DC on November 19, 2001.

Jane F. Garvey,

Administrator.

[FR Doc. 01–29272 Filed 11–21–01; 8:45 am]

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Federal Register

Vol. 66, No. 226

Friday, November 23, 2001

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

55067–55554 1
55555–55870 2
55871–56030 5
56031–56194 6
56195–56424 7
56425–56594 8
56595–56752 9
56753–56966 13
56967–57354 14
57355–57644 15
57645–57836 16
57837–58048 19
58049–58348 20
58349–58654 21
58655–58912 23

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:

7208 (See Proc. 7502) 57837
7463 (See Military Order of November 13, 2001) 57833
7463 (See EO 13235) 58343
7491 55555
7492 56031
7493 56425
7494 57627
7495 57631
7496 57633
7497 57635
7498 57637
7499 57639
7500 57641
7501 57643
7502 57837
7503 58049
7504 58347

Executive Orders:

12170 (See Notice of November 9, 2001) 56966
12667 (Revoked by 13233) 56025
12938 (See Notice of November 9, 2001) 56965
12958 (See Military Order of November 13, 2001) 57833
13067 (see Notice of October 31, 2001) 55869
13233 56025
13234 57355
13235 58343

Administrative Orders:

Notices:
Notice of October 31, 2001 55869
Notice of November 14, 1995 (See Notice of November 9, 2001) 56965
Notice of November 12, 1996 (See Notice of November 9, 2001) 56965
Notice of November 13, 1997 (See Notice of November 9, 2001) 56965
Notice of November 12, 1998 (See Notice of November 9, 2001) 56965
Notice of November 10, 1999 (See Notice of November 9, 2001) 56965
Notice of November 12, 2000 (See Notice of November 9, 2001) 56965
Notice of November 9, 2001 56965
Notice of November 9, 2001 56966
Memorandums:
Memorandums of November 9, 2001 57357
Memorandums of November 9, 2001 57359
Military Orders:
Military Order of November 13, 2001 57833

5 CFR

591 ..... 56738, 56751
630 ..... 55557, 56033
1201 57841
2634 55871

Proposed Rules:

591 56741

7 CFR

80 58349
300 56427
301 ..... 55067, 56428
319 55530
510 57841
905 56595
923 58350
930 ..... 56597, 58356, 58359
966 56599
984 58362
993 56602
1205 58051
1210 56386
3404 57842
3601 57843
3701 57844

Proposed Rules:

3 56247
1124 57889
1210 56391
1717 55130

8 CFR

3 56767
241 56967

9 CFR

93 ..... 55068, 56033
94 55872

Proposed Rules:

319 55601

10 CFR

2 55732

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT NOVEMBER 23, 2001

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Potatoes; Fresh Russet Potato Diversion Program; published 11-21-01

ENVIRONMENTAL PROTECTION AGENCY

Air pollution control:

State operating permits programs—

New Hampshire; published 9-24-01

West Virginia; published 10-9-01

Air quality implementation plans; √A√approval and promulgation; various States; air quality planning purposes; designation of areas:

Kentucky and Indiana; published 10-23-01

Air quality implementation plans; approval and promulgation; various States:

Kentucky; published 10-23-01

Texas; published 9-24-01

Hazardous waste:

Project XL program; site-specific projects—

US Filter Recovery Services Facility, Roseville, MN, et al.; published 5-22-01

HEALTH AND HUMAN SERVICES DEPARTMENT

Children and Families Administration

Foster care maintenance payments, adoption assistance, and child and family services:

Title IV-E foster care eligibility reviews and child and family services State plan reviews; published 11-23-01

HEALTH AND HUMAN SERVICES DEPARTMENT

Compassionate payments:

Ricky Ray Hemophilia Relief Fund Program; published 11-23-01

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Milk marketing orders:

Northeast et al.; comments due by 11-26-01; published 10-25-01 [FR 01-26901]

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Potatoes (Irish) grown in—

Colorado; comments due by 11-26-01; published 9-25-01 [FR 01-23655]

AGRICULTURE DEPARTMENT

Food Safety and Inspection Service

Meat and poultry inspection:

Transglutaminase enzyme and pork collagen use as binders; comments due by 11-30-01; published 10-31-01 [FR 01-27264]

COMMERCE DEPARTMENT

Export Administration Bureau

Export administration regulations:

Foreign policy-based export controls; effects on exporters and general public; comments due by 11-30-01; published 11-7-01 [FR 01-27878]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Caribbean, Gulf, and South Atlantic fisheries—

Caribbean Fishery Management Council; hearings; comments due by 11-26-01; published 11-5-01 [FR 01-27723]

Northeastern United States fisheries—

Atlantic herring; comments due by 11-28-01; published 10-29-01 [FR 01-27168]

Atlantic herring; correction; comments due by 11-28-01; published 11-6-01 [FR 01-27851]

ENVIRONMENTAL PROTECTION AGENCY

Air pollution control:

State operating permits programs—

New Jersey; comments due by 11-26-01; published 10-25-01 [FR 01-26928]

New York; comments due by 11-26-01; published 10-25-01 [FR 01-26927]

ENVIRONMENTAL PROTECTION AGENCY

Air programs:

Fuels and fuel additives—

Motorcycle fuel inlet restrictor exemption; gasoline containing lead or lead additives; prohibition for highway use; comments due by 11-30-01; published 10-31-01 [FR 01-27378]

ENVIRONMENTAL PROTECTION AGENCY

Air programs:

Fuels and fuel additives—

Motorcycle fuel inlet restrictor exemption; gasoline containing lead or lead additives; prohibition for highway use; comments due by 11-30-01; published 10-31-01 [FR 01-27379]

ENVIRONMENTAL PROTECTION AGENCY

Air programs; approval and promulgation; State plans for designated facilities and pollutants:

Puerto Rico; comments due by 11-29-01; published 10-30-01 [FR 01-27283]

ENVIRONMENTAL PROTECTION AGENCY

Air programs; approval and promulgation; State plans for designated facilitiesand pollutants:

Puerto Rico; comments due by 11-29-01; published 10-30-01 [FR 01-27284]

Air quality implementation plans; approval and promulgation; various States:

Texas; comments due by 11-29-01; published 10-30-01 [FR 01-27108]

Electronic reporting establishment; electronic records; comments due by 11-29-01; published 8-31-01 [FR 01-21810]

Hazardous waste:

Project XL program; site-specific projects—

NASA White Sands Test Facility, Las Cruces, NM; comments due by 11-30-01; published 10-31-01 [FR 01-27380]

ENVIRONMENTAL PROTECTION AGENCY

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Zoxamide and its metabolites; comments due by 11-26-01; published 9-26-01 [FR 01-23640]

ENVIRONMENTAL PROTECTION AGENCY

Toxic substances:

Significant new uses—

Propanedioic acid, etc.; comments due by 11-29-01; published 10-30-01 [FR 01-27291]

Water pollution control:

Ocean dumping; site designations—

Atlantic Ocean offshore Charleston, SC; comments due by 11-26-01; published 10-10-01 [FR 01-25411]

Water programs:

Pollutants analysis test procedures; guidelines—

Whole effluent toxcity test methods; comments due by 11-27-01; published 9-28-01 [FR 01-24374]

FEDERAL COMMUNICATIONS COMMISSION

Radio stations; table of assignments:

Georgia; comments due by 11-26-01; published 10-19-01 [FR 01-26374]

New Mexico and Texas; comments due by 11-26-01; published 10-17-01 [FR 01-26067]

Texas; comments due by 11-26-01; published 10-19-01 [FR 01-26373]

FEDERAL RESERVE SYSTEM

International banking operations (Regulation K):

International lending supervision; comments due by 12-1-01; published 10-26-01 [FR 01-26731]

FEDERAL TRADE COMMISSION

Children's Online Privacy Protection Act; implementation:

Parental consent; comments due by 11-30-01; published 10-31-01 [FR 01-27390]

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Low income housing:

Section 8 Management Assessment Program; lease-up indicator; comments due by 11-30-01; published 10-1-01 [FR 01-24434]

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species:
Findings on petitions, etc.—
Lower Kootenai River burbot; comments due by 11-27-01; published 9-28-01 [FR 01-23913]

JUSTICE DEPARTMENT
Grants:
September 11th victim compensation fund; comments due by 11-26-01; published 11-5-01 [FR 01-27821]

LABOR DEPARTMENT
Labor-Management Standards Office
Federal contractors and subcontractors:
Employee rights concerning union dues or fees payment; comments due by 11-30-01; published 10-1-01 [FR 01-24320]

PERSONNEL MANAGEMENT OFFICE
Health benefits, Federal employees:
Health insurance premiums—
TRICARE-eligible's enrollment suspension; comments due by 11-26-01; published 9-26-01 [FR 01-24108]

TRANSPORTATION DEPARTMENT
Coast Guard
Tank vessels; tank level pressure monitoring devices; comments due by 11-30-01; published 10-1-01 [FR 01-24493]

TRANSPORTATION DEPARTMENT
Aviation economic regulations:
Air carrier traffic and capacity data by nonstop segment and on-flight market; reporting requirements; comments due by 11-26-01; published 8-28-01 [FR 01-21457]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Airbus; comments due by 11-26-01; published 10-26-01 [FR 01-26955]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Airbus; comments due by 11-28-01; published 10-29-01 [FR 01-26860]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
BAE Systems (Operations) Ltd.; comments due by 11-28-01; published 10-29-01 [FR 01-27072]
Bombardier; comments due by 11-29-01; published 10-30-01 [FR 01-27216]
General Electric Co.; comments due by 11-26-01; published 9-27-01 [FR 01-24274]
Israel Aircraft Industries, Ltd.; comments due by 11-28-01; published 10-29-01 [FR 01-27071]
Pilatus Aircraft Ltd.; comments due by 11-30-01; published 10-24-01 [FR 01-26587]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Rolls-Royce plc; comments due by 11-26-01; published 9-26-01 [FR 01-24023]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Rolls-Royce plc; comments due by 11-27-01; published 9-28-01 [FR 01-24271]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness standards:
Special conditions—
Boeing 727-100/-200 series airplanes; comments due by 11-28-01; published 10-29-01 [FR 01-27160]

TRANSPORTATION DEPARTMENT
National Highway Traffic Safety Administration
Motor vehicle safety standards:
Lamps, reflective devices, and associated equipment—
Glare from headlamps and other front mounted lamps; comments due by 11-27-01; published 9-28-01 [FR 01-24430]

TRANSPORTATION DEPARTMENT
Research and Special Programs Administration
Hazardous materials:
Hazardous materials transportation—
Loading, unloading, and storage; comments due by 11-30-01; published 8-2-01 [FR 01-19335]
Loading, unloading, and storage; meetings cancelled; comments due by 11-30-01; published 10-2-01 [FR 01-24539]

TREASURY DEPARTMENT
Currency and foreign transactions; financial reporting and recordkeeping requirements:
Bank Secrecy Act; implementation—
Funds transmittal by financial institutions; extension of conditional exceptions to strict operation of Travel Rule; comments due by 12-1-01; published 6-18-01 [FR 01-15224]
Privacy Act; implementation; comments due by 11-26-01; published 10-26-01 [FR 01-27003]

VETERANS AFFAIRS DEPARTMENT
Acquisition regulations:
Construction and architect-engineer contracts; comments due by 11-26-01; published 9-27-01 [FR 01-23772]
Disabilties rating schedule:
Substantially gainful employment, inability of individual to engage in; total disability ratings; comments due by 11-30-01; published 10-1-01 [FR 01-24272]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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S. 1447/P.L. 107–71

Aviation and Transportation Security Act (Nov. 19, 2001; 115 Stat. 597)

Last List November 20, 2001

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